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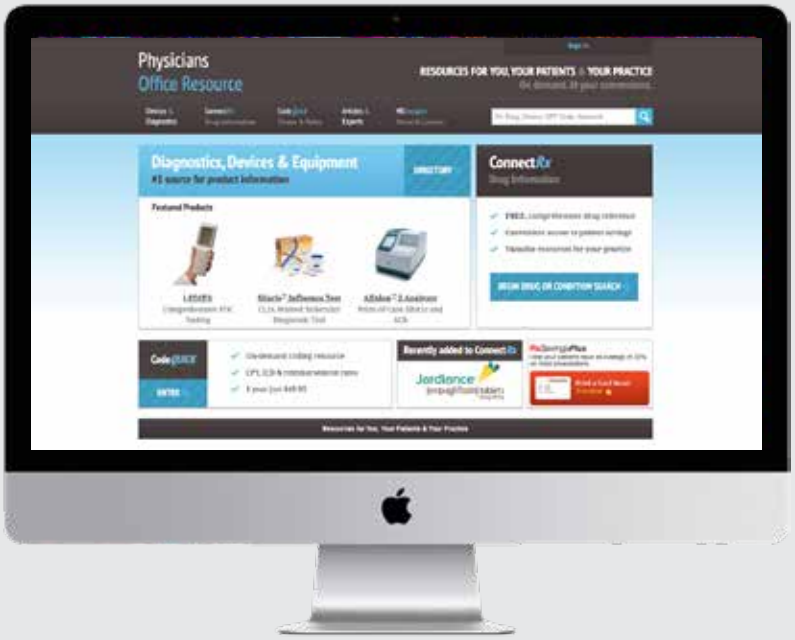
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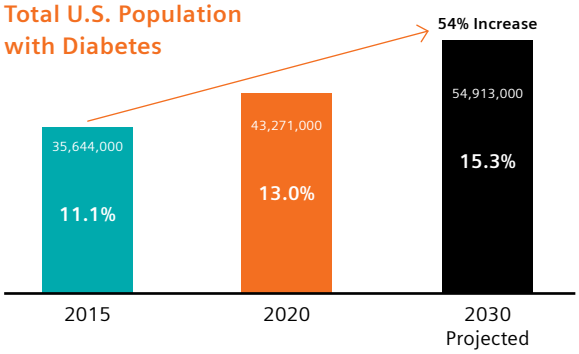


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1. Rowley, William R et al. "Diabetes 2030: Insights from Yesterday, Today, and Future Trends." Population health management vol. 20,1 (2017): 6-12. doi:10.1089/pop.2015.0181.

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THE PATH FORWARD

Jaypirca® pirtobrutinib 50, 100 mg tablets

Jaypirca can help move adult patients with CLL/SLL forward **after ≥2 prior lines, including a BTKi and BCL2i**[1,2]



Indication

Jaypirca is a kinase inhibitor indicated for the treatment of adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) who have received at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor.

This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Important Safety Information for Jaypirca

Infections: Fatal and serious infections (including bacterial, viral, fungal) and opportunistic infections occurred in Jaypirca-treated patients. In a clinical trial, Grade ≥3 infections occurred in 24% of patients with hematologic malignancies, most commonly pneumonia (14%); fatal infections occurred in 4.4%. Sepsis (6%) and febrile neutropenia (4%) occurred. In patients with CLL/SLL, Grade ≥3 infections occurred (32%), with fatal infections occurring in 8%. Opportunistic infections included *Pneumocystis jirovecii* pneumonia and fungal infection. Consider prophylaxis, including vaccinations and antimicrobial prophylaxis, in patients at increased risk for infection, including opportunistic infections. Monitor patients for signs and symptoms, evaluate promptly, and treat appropriately. Based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca.

Hemorrhage: Fatal and serious hemorrhage has occurred with Jaypirca. Major hemorrhage (Grade ≥3 bleeding or any central nervous system bleeding) occurred in 3% of patients, including gastrointestinal hemorrhage; fatal hemorrhage occurred (0.3%). Bleeding of any grade, excluding bruising and petechiae, occurred in 17%. Major hemorrhage occurred in patients taking Jaypirca with (0.7%) and without (2.3%) antithrombotic agents. Consider risks/benefits of co-administering antithrombotic agents with Jaypirca. Monitor patients for signs of bleeding. Based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca. Consider benefit/risk of withholding Jaypirca 3-7 days pre- and post-surgery depending on type of surgery and bleeding risk.

Cytopenias: Jaypirca can cause cytopenias, including neutropenia, thrombocytopenia, and anemia. In a clinical trial, Grade 3 or 4 cytopenias, including decreased neutrophils (26%), decreased platelets (12%), and decreased hemoglobin (12%), developed in Jaypirca-treated patients. Grade 4 decreased neutrophils (14%) and Grade 4 decreased platelets (6%) developed. Monitor complete blood counts regularly during treatment. Based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca.

Cardiac Arrhythmias: Cardiac arrhythmias occurred in patients who received Jaypirca. In a clinical trial of patients with hematologic malignancies, atrial fibrillation or flutter were reported in 3.2% of Jaypirca-treated patients, with Grade 3 or 4 atrial fibrillation or flutter in 1.5%. Other serious cardiac arrhythmias such as supraventricular tachycardia and cardiac arrest occurred (0.5%). Patients with cardiac risk factors such as hypertension or previous arrhythmias may be at increased risk. Monitor for signs and symptoms of arrhythmias (e.g., palpitations, dizziness, syncope, dyspnea) and manage appropriately. Based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca.

Second Primary Malignancies: Second primary malignancies, including non-skin carcinomas, developed in 9% of Jaypirca-treated patients. The most frequent malignancy was non-melanoma skin cancer (4.6%). Other second primary malignancies included solid tumors (including genitourinary and breast cancers) and melanoma. Advise patients to use sun protection and monitor for development of second primary malignancies.

Embryo-Fetal Toxicity: Jaypirca can cause fetal harm in pregnant women. Administration of pirtobrutinib to pregnant rats during organogenesis caused embryo-fetal toxicity, including embryo-fetal mortality and malformations at maternal exposures (AUC) approximately 3-times the recommended 200 mg/day dose. Advise pregnant women of potential fetal risk and females of reproductive potential to use effective contraception during treatment and for one week after last dose.

Adverse Reactions (ARs) in Patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

Serious ARs occurred in 56% of patients. Serious ARs occurring in ≥5% of patients were pneumonia (18%), COVID-19 (9%), sepsis (7%), and febrile neutropenia (7%). **Fatal ARs** within 28 days of last Jaypirca dose occurred in 11% of patients, most commonly due to infections (10%) including sepsis (5%) and COVID-19 (2.7%).

Dose Modifications and Discontinuations: ARs led to dose reductions in 3.6%, treatment interruption in 42%, and permanent discontinuation of Jaypirca in 9% of patients. ARs resulting in dose reductions in >1% of patients included neutropenia. ARs resulting in treatment interruptions in >5% of patients included pneumonia, neutropenia, febrile neutropenia, and COVID-19. ARs resulting in permanent discontinuation in >1% of patients

BCL-2=B-cell lymphoma 2; BCL2i=B-cell lymphoma 2 inhibitor; BTK=Bruton's tyrosine kinase; BTKi=Bruton's tyrosine kinase inhibitor.

The first-and-only approved reversible (noncovalent) BTK inhibitor[1]

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CLL/SLL

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Important Safety Information for Jaypirca (cont'd)

included second primary malignancy, COVID-19, and sepsis.

ARs (all Grades %; Grade 3-4 %) in ≥10% of Patients: fatigue (36; 2.7), bruising (36; -), cough (33; -), musculoskeletal pain (32; 0.9), COVID-19 (28; 7), pneumonia (27; 16), diarrhea (26; -), abdominal pain (25; 2.7), dyspnea (22; 2.7), hemorrhage (22; 2.7), edema (21; -), nausea (21; -), pyrexia (20; 2.7), headache (20; 0.9), arthritis/arthralgia (19; 1.8), rash (19; 0.9), peripheral neuropathy (16; 3.6), dizziness (15; -), fall (14; 0.9), constipation (14; -), insomnia (14; -), upper respiratory tract infections (13; 2.7), second primary malignancy (13; 2.7), renal insufficiency (12; 6), hypertension (12; 5), neurological changes (12; 2.7), mucositis (12; 0.9), decreased appetite (12; -), respiratory tract infection (11; 1.8), supraventricular tachycardia (10; 5).

Select Laboratory Abnormalities (all Grades %; Grade 3 or 4 %) that Worsened from Baseline in ≥20% of Patients: neutrophil count decreased (63; 45), hemoglobin decreased (48; 19), calcium decreased (40; 2.8), platelet count decreased (30; 15), sodium decreased (30; -), lymphocyte count decreased (23; 8), ALT increased (23; 2.8), AST increased (23; 1.9), creatinine increased (23; -), lipase increased (21; 7), alkaline phosphatase increased (21; -). Grade 4 laboratory abnormalities in >5% of patients included neutrophils decreased (23).

The most common (≥20%) ARs in the BRUIN pooled safety population of patients with hematologic malignancies (n=593) were decreased neutrophil count (46%), decreased hemoglobin (39%), fatigue (32%), decreased lymphocyte count (31%), musculoskeletal pain (30%), decreased platelet count (29%), diarrhea (24%), COVID-19 (22%), bruising (21%), cough (20%).

Drug Interactions

Strong CYP3A Inhibitors: Concomitant use with Jaypirca increased pirtobrutinib systemic exposure, which may increase risk of Jaypirca ARs. Avoid use of strong CYP3A inhibitors with Jaypirca. If concomitant use is unavoidable, reduce Jaypirca dosage according to approved labeling.

Strong or Moderate CYP3A Inducers: Concomitant use with Jaypirca decreased pirtobrutinib systemic exposure, which may reduce Jaypirca efficacy. Avoid concomitant use of Jaypirca with strong or moderate CYP3A inducers. If concomitant use with moderate CYP3A inducers is unavoidable, increase Jaypirca dosage according to approved labeling.

Sensitive CYP2C8, CYP2C19, CYP3A, P-gp, or BCRP Substrates: Concomitant use with Jaypirca increased their plasma concentrations, which may increase risk of adverse reactions related to these substrates for drugs that are sensitive to minimal concentration changes. Follow recommendations for these sensitive substrates in their approved labeling.

Use in Special Populations

Pregnancy and Lactation: Due to potential for Jaypirca to cause fetal harm, verify pregnancy status in females of reproductive potential prior to starting Jaypirca and advise use of effective contraception during treatment and for one week after last dose. Presence of pirtobrutinib in human milk is unknown. Advise women not to breastfeed while taking Jaypirca and for one week after last dose.

Geriatric Use: In the pooled safety population of patients with hematologic malignancies, patients aged ≥65 years experienced higher rates of Grade ≥3 ARs and serious ARs compared to patients <65 years of age.

Renal Impairment: Severe renal impairment increases pirtobrutinib exposure. Reduce Jaypirca dosage in patients with severe renal impairment according to approved labeling.

PT HCP ISI CLL DEC2023

Please see Brief Summary of Prescribing Information for Jaypirca on subsequent pages.

References: 1. Jaypirca. Prescribing Information. Lilly USA, LLC. 2. Mato AR, Shah NN, Jurczak W, et al. Pirtobrutinib in relapsed or refractory B-cell malignancies (BRUIN): a phase 1/2 study. *Lancet*. 2021;397(10277):892-901.

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pirtobrutinib 50, 100 mg tablets

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Jaypirca® (pirtobrutinib) tablets, for oral use
Initial U.S. Approval: 2023

Brief Summary: Consult the package insert for complete prescribing information.

INDICATIONS AND USAGE

Jaypirca is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Jaypirca is indicated for the treatment of adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) who have received at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

CONTRAINDICATIONS: None

WARNINGS AND PRECAUTIONS

Infections: Fatal and serious infections (including bacterial, viral, or fungal infections) and opportunistic infections have occurred in patients treated with Jaypirca. In the clinical trial, Grade 3 or higher infections occurred in 24% of 593 patients, most commonly pneumonia (14%), with fatal infections occurring in 4.4% of patients. Sepsis occurred in 6% of patients and febrile neutropenia in 4%. In patients with CLL/SLL, Grade 3 or higher infections occurred in 32% of patients, with fatal infections occurring in 8%. Opportunistic infections after treatment with Jaypirca have included, but are not limited to, *Pneumocystis jirovecii* pneumonia and fungal infection *[see Adverse Reactions]*.

Consider prophylaxis, including vaccinations and antimicrobial prophylaxis, in patients who are at increased risk for infections, including opportunistic infections. Monitor patients for signs and symptoms of infection, evaluate promptly, and treat appropriately. Based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca *[see Dosage and Administration]*.

Hemorrhage: Fatal and serious hemorrhage has occurred with Jaypirca. Major hemorrhage (defined as Grade 3 or higher bleeding or any central nervous system bleeding) occurred in 3% of 593 patients treated with Jaypirca, including gastrointestinal hemorrhage; fatal hemorrhage occurred in 0.3% of patients. Bleeding of any grade, excluding bruising and petechiae, occurred in 17% of patients.

Major hemorrhage occurred in 2.3% of patients taking Jaypirca without antithrombotic agents and 0.7% of patients taking Jaypirca with antithrombotic agents. Consider the risks and benefits of antithrombotic agents when co-administered with Jaypirca. Monitor patients for signs of bleeding. Based on severity of bleeding, reduce dose, temporarily withhold, or permanently discontinue Jaypirca *[see Dosage and Administration]*.

Consider the benefit-risk of withholding Jaypirca for 3 to 7 days pre- and post-surgery depending upon the type of surgery and risk of bleeding.

Cytopenias: Jaypirca can cause cytopenias, including neutropenia, thrombocytopenia, and anemia. In the clinical trial, Grade 3 or 4 cytopenias, including decreased neutrophils (26%), decreased platelets (12%), and decreased hemoglobin (12%), developed in patients treated with Jaypirca. Grade 4 decreased neutrophils developed in 14% of patients and Grade 4 decreased platelets developed in 6% of patients *[see Adverse Reactions]*.

Monitor complete blood counts regularly during treatment. Based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca *[see Dosage and Administration]*.

Cardiac Arrhythmias: Cardiac arrhythmias, including atrial fibrillation and atrial flutter, were reported in recipients of JAYPIRCA. Atrial fibrillation or flutter were reported in 3.2% of patients, with Grade 3 or 4 atrial fibrillation or flutter reported in 1.5% of 593 patients in the clinical trial *[see Adverse Reactions]*. Other serious cardiac arrhythmias such as supraventricular tachycardia and cardiac arrest occurred in 0.5% of patients. Patients with cardiac risk factors, such as hypertension or previous arrhythmias may be at increased risk.

Monitor for signs and symptoms of arrhythmias (e.g., palpitations, dizziness, syncope, dyspnea) and manage appropriately. Based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca *[see Dosage and Administration]*.

Second Primary Malignancies: Second primary malignancies, including non-skin carcinomas, developed in 9% of 593 patients treated with Jaypirca monotherapy. The most frequent malignancy was non-melanoma skin cancer, reported in 4.6% of 593 patients. Other second primary malignancies included solid tumors (including genitourinary and breast cancers) and melanoma. Advise patients to use sun protection and monitor patients for the development of second primary malignancies.

Embryo-Fetal Toxicity: Based on findings in animals, Jaypirca can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of pirtobrutinib to pregnant rats during the period of organogenesis caused embryo-fetal toxicity including embryo-fetal mortality and malformations at maternal exposures (AUC) approximately 3-times the recommended dose of 200 mg once daily. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with Jaypirca and for one week after the last dose *[see Use in Specific Populations]*.

ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling *[see Warnings and Precautions]*:
Infections, Hemorrhage, Cytopenias, Atrial Fibrillation and Atrial Flutter, and Second Primary Malignancies

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be compared to rates in the clinical trials of another drug and may not reflect the rates observed in the general patient population.

The data in the WARNINGS AND PRECAUTIONS reflect exposure to Jaypirca as a single-agent, administered at 200 mg once daily in 593 patients with hematologic malignancies in the BRUIN study. Among these 593 patients, the median duration of exposure was 10 months, 62% were exposed for at least 6 months and 45% were exposed for at least one year.

In this pooled safety population, the most common (> 20%) adverse reactions, including laboratory abnormalities, were decreased neutrophil count (46%), decreased hemoglobin (39%), fatigue (32%), decreased lymphocyte count (31%), musculoskeletal pain (30%), decreased platelet count (29%), diarrhea (24%), COVID-19 (22%), bruising (21%), and cough (20%).

Mantle Cell Lymphoma

BRUIN: The safety of Jaypirca was evaluated in the BRUIN trial in patients with MCL who received a prior BTK inhibitor. The trial required a platelet count > 50 x 10^9/L, absolute neutrophil count ≥ 0.75 x 10^9/L, hepatic transaminases ≤ 2.5 times upper limit of normal (ULN), and an ECOG performance status of 0 to 2. The trial excluded patients with active central nervous system (CNS) involvement by lymphoma, significant cardiovascular disease, major bleeding or grade ≥ 3 arrhythmia with a prior BTK inhibitor, prolonged QTc interval, or need for a strong CYP3A inhibitor or inducer or strong P-gp inhibitor.

Patients received Jaypirca 200 mg orally once daily until disease progression or unacceptable toxicity (n = 128); 36% were exposed for 6 months or longer and 10% were exposed for at least one year. The median number of prior therapies was 3 (range: 1-9). The median age was 71 years (range: 46 to 88 years) and 80% of patients were male. Race was reported for all patients; 78% were White, 14% were Asian, 2.3% were Black, and 2.3% were Hispanic or Latino.

Serious adverse reactions occurred in 38% of patients who received Jaypirca. Serious adverse reactions that occurred in > 2% of patients were pneumonia (14%), COVID-19 (4.7%), musculoskeletal pain (3.9%), hemorrhage (2.3%), pleural effusion (2.3%), and sepsis (2.3%). Fatal adverse reactions within 28 days of the last dose of Jaypirca occurred in 7% of patients, most commonly due to infections (4.7%) including COVID-19 (3.1% of all patients).

Adverse reactions led to dose reductions in 4.7%, treatment interruption in 32%, and permanent discontinuation of Jaypirca in 9%. Adverse reactions that resulted in dosage modification in > 5% of patients included pneumonia and neutropenia. Adverse reactions which resulted in permanent discontinuation of Jaypirca in > 1% of patients included pneumonia.

The most common adverse reactions (≥ 15%), excluding laboratory terms, were fatigue, musculoskeletal pain, diarrhea, edema, dyspnea, pneumonia, and bruising.

Table 1 summarizes select adverse reactions in BRUIN.

Table 1: Adverse Reactions (≥ 10%) in Patients with MCL Who Received Jaypirca

	Jaypirca 200 mg once daily	
	N=128	
Adverse Reactions[a]	**All Grades (%)**	**Grade 3-4 (%)**
General Disorders		
Fatigue	29	1.6
Edema	18	0.8
Fever	13	-
Musculoskeletal and Connective Tissue Disorders		
Musculoskeletal pain	27	3.9
Arthritis or arthralgia	12	0.8
Gastrointestinal Disorders		
Diarrhea	19	-
Constipation	13	-
Abdominal pain	11	0.8
Nausea	11	-

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Table 1: Adverse Reactions (≥ 10%) in Patients with MCL Who Received Jaypirca (Cont.)

	Jaypirca 200 mg once daily N=128	
Adverse Reactions[a]	**All Grades (%)**	**Grade 3-4 (%)**
Respiratory, thoracic, and mediastinal disorders		
Dyspnea	17	2.3
Cough	14	-
Injury		
Bruising	16	-
Infections		
Pneumonia	16[b]	14
Upper respiratory tract infections	10	0.8
Nervous system disorders		
Peripheral neuropathy	14	0.8
Dizziness	10	-
Skin and subcutaneous disorders		
Rash	14	-
Vascular disorders		
Hemorrhage	11[c]	3.1

[a]Each term listed includes other related terms
[b]includes 1 fatality from COVID-19 pneumonia
[c]includes 1 fatality from hemorrhage

Clinically relevant adverse reactions in < 10% include vision changes, memory changes, headache, urinary tract infection, herpesvirus infection, and tumor lysis syndrome.

Table 2 summarizes laboratory abnormalities in BRUIN.

Table 2: Select Laboratory Abnormalities (≥ 10%) That Worsened from Baseline In Patients with MCL Who Received Jaypirca

Laboratory Abnormality	Jaypirca[a] 200 mg once daily	
	All Grades (%)	**Grade 3 or 4 (%)**
Hematology		
Hemoglobin decreased	42	9
Platelet count decreased	39	14
Neutrophil count decreased	36	16
Lymphocyte count decreased	32	15
Chemistry		
Creatinine increased	30	1.6
Calcium decreased	19	1.6
AST increased	17	1.6
Potassium decreased	13	1.6
Sodium decreased	13	-
Lipase increased	12	4.4
Alkaline phosphatase increased	11	-
ALT increased	11	1.6
Potassium increased	11	0.8

[a] The denominator used to calculate the rate varied from 90 to 127 based on the number of patients with a baseline value and at least one post-treatment value.

Grade 4 laboratory abnormalities in > 5% of patients included neutrophils decreased (10%), platelets decreased (7%), and lymphocytes decreased (6%).

Lymphocytosis: Upon initiation of Jaypirca, a temporary increase in lymphocyte counts (defined as absolute lymphocyte count increased ≥ 50% from baseline and a post-baseline value ≥ 5,000/µL) occurred in 34% of MCL patients in BRUIN. The median time to onset of lymphocytosis was 1.1 weeks, with 75% of cases occurring within 2.1 weeks, and the median duration was 11 weeks.

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

BRUIN: The safety of Jaypirca was evaluated in the BRUIN trial in 110 patients with CLL/SLL, with 98% receiving at least two prior lines of systemic therapy including a BTK inhibitor and a BCL-2 inhibitor. The trial required a platelet count ≥ 50 x 10^9/L, absolute neutrophil count > 0.75 x 10^9/L, hepatic transaminases < 2.5 times upper limit of normal (ULN), and an ECOG performance status of 0 to 2. The trial excluded patients with active central nervous system (CNS) involvement by lymphoma, significant cardiovascular disease, major bleeding, uncontrolled or symptomatic arrhythmias, prolonged QTc interval, or need for a strong CYP3A inhibitor or inducer or strong P-gp inhibitor.

Patients received Jaypirca 200 mg orally once daily until disease progression or unacceptable toxicity (N = 110); 60% were exposed for at least 1 year and 14% were exposed for at least two years. The median age was 68 years (range: 41 to 88 years) and 67% of patients were male. Race was reported in 110 (100%) patients; of these patients, 89% were White, 4.5% were Black, 1.8% were Asian, and 1.8% were Hispanic or Latino. The median number of prior therapies was 5 (range: 1-11).

Serious adverse reactions occurred in 56% of patients who received Jaypirca. Serious adverse reactions that occurred in ≥ 5% of patients were pneumonia (18%), COVID-19 (9%), sepsis (7%), and febrile neutropenia (7%). Fatal adverse reactions within 28 days of the last dose of Jaypirca occurred in 11% of patients, most commonly due to infections (10%), including sepsis (5%) and COVID-19 (2.7%).

Adverse reactions led to dose reductions in 3.6%, treatment interruption in 42%, and permanent discontinuation of Jaypirca in 9%. Adverse reactions which resulted in dose reductions of Jaypirca in > 1% of patients included neutropenia. Adverse reactions which resulted in treatment interruptions of Jaypirca in >5% of patients included pneumonia, neutropenia, febrile neutropenia, and COVID-19. Adverse reactions which resulted in permanent discontinuation of Jaypirca in > 1% of patients included second primary malignancy, COVID-19, and sepsis.

The most common adverse reactions (≥ 20%), excluding laboratory terms, were fatigue, bruising, cough, musculoskeletal pain, COVID-19, diarrhea, pneumonia, abdominal pain, dyspnea, hemorrhage, edema, nausea, pyrexia, and headache.

Table 3 summarizes select adverse reactions for patients treated in BRUIN.

Table 3: Adverse Reactions (≥ 10%) in Patients with CLL/SLL Who Received Jaypirca

	Jaypirca 200 mg once daily N=110	
Adverse Reactions[a]	**All Grades (%)**	**Grade 3-4 (%)**
General Disorders		
Fatigue	36	2.7
Edema	21	0
Pyrexia	20	2.7
Injury		
Bruising	36	0
Fall	14	0.9
Respiratory, thoracic, and mediastinal disorders		
Cough	33	0
Dyspnea	22	2.7
Mucositis	12	0.9
Musculoskeletal and Connective Tissue Disorders		
Musculoskeletal pain	32	0.9
Arthritis or arthalgia	19	1.8
Infections		
COVID-19	28[b]	7
Pneumonia	27[c]	16
Upper respiratory tract infections	13	2.7
Respiratory tract infection	11	1.8
Gastrointestinal Disorders		
Diarrhea	26	0
Abdominal pain	25	2.7
Nausea	21	0
Constipation	14	0
Vascular disorders		
Hemorrhage	22[d]	2.7
Hypertension	12	5
Nervous system disorders		
Headache	20	0.9
Peripheral neuropathy	16	3.6
Dizziness	15	0
Neurological changes	12[e]	2.7
Skin and subcutaneous disorders		
Rash	19	0.9

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Table 3: Adverse Reactions (≥ 10%) in Patients with CLL/SLL Who Received Jaypirca (Cont.)

	Jaypirca 200 mg once daily N=110	
Adverse Reactions[a]	**All Grades (%)**	**Grade 3-4 (%)**
Psychiatric disorders		
Insomnia	14	0
Neoplasms benign, malignant and unspecified		
Second primary malignancy	13[f]	2.7
Renal and urinary disorders		
Renal insufficiency	12[g]	6
Metabolism and nutrition disorders		
Decreased appetite	12	0
Cardiac disorders		
Supraventricular tachycardia	10[h]	5

[a] Each term listed includes other related terms.
[b] Includes COVID-19 pneumonia. Includes 1 fatality from COVID-19 and 2 fatalities from COVID-19 pneumonia.
[c] Includes COVID-19 pneumonia. Includes 2 fatalities from COVID-19 pneumonia and 1 fatality from pneumonia.
[d] Includes preferred terms hemorrhage, intracranial hemorrhage, and gastrointestinal hemorrhage.
[e] Includes preferred terms memory impairment, confusional state, encephalopathy, mental status changes.
[f] Includes preferred terms second primary malignancy and nonmelanoma skin cancers. 1 fatality from metastatic malignant melanoma.
[g] Includes preferred terms renal failure, chronic kidney disease, acute kidney injury.
[h] Includes preferred terms supraventricular tachycardia, sinus tachycardia, atrial fibrillation.

Clinically relevant adverse reactions in < 10% include vision changes, lower respiratory tract infection, urinary tract infection, herpesvirus infection, and tumor lysis syndrome.

Table 4 summarizes laboratory abnormalities in BRUIN.

Table 4: Select Laboratory Abnormalities (≥ 20%) That Worsened from Baseline in Patients with CLL/SLL Who Received Jaypirca

Laboratory Abnormality	Jaypirca[a] 200 mg once daily	
	All Grades (%)	**Grade 3 or 4 (%)**
Hematology		
Neutrophil count decreased	63	45
Hemoglobin decreased	48	19
Platelet count decreased	30	15
Lymphocyte count decreased	23	8
Chemistry		
Calcium decreased	40	2.8
Sodium decreased	30	0
ALT increased	23	2.8
AST increased	23	1.9
Creatinine increased	23	0
Lipase increased	21	7
Alkaline phosphatase increased	21	0

[a] The denominator used to calculate the rate varied from 83 to 108 based on the number of patients with a baseline value and at least one post-treatment value.

Grade 4 laboratory abnormalities in > 5% of patients included neutrophils decreased (23%).

Lymphocytosis: Upon initiation of Jaypirca, a temporary increase in lymphocyte counts (defined as absolute lymphocyte count increased ≥ 50% from baseline and a post-baseline value ≥ 5,000/μL) occurred in 64% of CLL/SLL patients in BRUIN. The median time to onset of lymphocytosis was 1.1 weeks, with 75% of cases occurring within 1.1 weeks, and the median duration was 19 weeks.

DRUG INTERACTIONS

Effect of Other Drugs on Jaypirca

Strong CYP3A Inhibitors: Pirtobrutinib is a CYP3A substrate. Concomitant use of Jaypirca with a strong CYP3A inhibitor increased pirtobrutinib systemic exposure, which may increase the risk of Jaypirca adverse reactions. Avoid concomitant use of strong CYP3A inhibitors during treatment with Jaypirca. If concomitant use of strong CYP3A inhibitors is unavoidable, reduce the Jaypirca dosage *[see Dosage and Administration]*.

Strong or Moderate CYP3A Inducers: Concomitant use of Jaypirca with a strong or moderate CYP3A inducer decreased pirtobrutinib systemic exposure, which may reduce Jaypirca efficacy. Avoid concomitant use of Jaypirca with strong or moderate CYP3A inducers. If concomitant use of moderate CYP3A inducers is unavoidable, increase the Jaypirca dosage *[see Dosage and Administration]*.

Effect of Jaypirca on Other Drugs

Sensitive CYP2C8, CYP2C19, CYP3A, P-gp, or BCRP Substrates: Jaypirca is a P-gp inhibitor, a moderate CYP2C8 and BCRP inhibitor, and a weak CYP2C19 and CYP3A inhibitor. Concomitant use of Jaypirca with sensitive P-gp, CYP2C8, BCRP, CYP2C19, or CYP3A substrates increased their plasma concentrations, which may increase the risk of adverse reactions related to these substrates for drugs which are sensitive to minimal concentration changes. Follow recommendations for sensitive CYP2C8, CYP2C19, CYP3A, P-gp, or BCRP substrates provided in their approved product labeling.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary
Based on findings from animal studies, Jaypirca can cause fetal harm when administered to a pregnant woman. There are no available data on Jaypirca use in pregnant women to evaluate for a drug-associated risk. In an animal reproduction study, administration of pirtobrutinib to pregnant rats during organogenesis resulted in adverse developmental outcomes, including structural abnormalities, altered fetal growth, and embryo-fetal mortality, at maternal exposures approximately 3-times those in patients at the recommended daily dose of 200 mg *(see Data)*. Advise pregnant women of the potential risk to a fetus.

The background risk in the U.S. general population of major birth defects is 2% to 4% and of miscarriage is 15% to 20% of clinically recognized pregnancies.

Data
Animal Data: In an embryo-fetal development study in rats, pregnant animals were administered oral doses of pirtobrutinib at up to 500 mg/kg twice daily during the period of organogenesis. Doses > 375 mg/kg twice daily caused decreased fetal body weights and increased incidence of malformations and variations in the urinary tract (including absent or abnormal ureters and kidneys), reproductive tract (malpositioned ovaries and misshapen uterus), and bone (misshapen sternebrae). At 500 mg/kg twice daily, total resorption was observed. At 375 mg/kg twice daily in rats, the maternal systemic exposures (AUC) were approximately 3 times the human exposure at 200 mg once daily.

Lactation

Risk Summary
There are no data on the presence of pirtobrutinib in human milk or the effects on the breastfed child or milk production. Because of the potential for serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment with Jaypirca and for one week after the last dose.

Females and Males of Reproductive Potential: Based on findings from animal studies, Jaypirca can cause fetal harm when administered to a pregnant woman *[see Use in Specific Populations]*.

Pregnancy Testing
Verify pregnancy status in females of reproductive potential prior to initiating Jaypirca.

Contraception
Females: Advise females of reproductive potential to use effective contraception during treatment with Jaypirca and for one week after the last dose.

Pediatric Use: Safety and effectiveness of Jaypirca have not been established in pediatric patients.

Geriatric Use: Of the patients with MCL who received the 200 mg dose of Jaypirca in BRUIN, 93 (78%) were 65 years of age and older and 39 (33%) were 75 years and older. Clinical studies of Jaypirca did not include sufficient numbers of patients with MCL who were less than 65 years of age to determine whether older patients respond differently from younger adult patients. Of the patients with CLL/SLL who received the 200 mg once daily dose of Jaypirca in BRUIN, 68 (63%) were 65 years of age and older and 21 (19%) were 75 years and older. No overall differences in effectiveness were observed between younger and older patients.

In the pooled safety population in patients with hematologic malignancies, 401 (68%) were 65 years of age and older, while 154 (26%) were 75 years of age and older. Patients aged 65 years and older experienced higher rates of Grade 3 and higher adverse reactions and serious adverse reactions compared to patients who were less than 65 years of age.

Renal Impairment: Severe renal impairment (eGFR 15-29 mL/min) increases pirtobrutinib exposure. Reduce the Jaypirca dosage in patients with severe renal impairment *[see Dosage and Administration]*. No dosage adjustment of Jaypirca is recommended in patients with mild (60-89 mL/min) or moderate (30-59 mL/min) renal impairment.

Hepatic Impairment: No dosage adjustment of Jaypirca is recommended in patients with mild hepatic impairment (total bilirubin ≤ upper limit of normal (ULN) and aspartate aminotransferase (AST) > ULN or total bilirubin > 1 to 1.5 × ULN and any AST), moderate hepatic impairment (total bilirubin > 1.5 to 3 × ULN and any AST), or severe hepatic impairment (total bilirubin > 3 × ULN and any AST).

Jaypirca® (pirtobrutinib) tablets, for oral use PT HCP BS DEC2023

DOSAGE AND ADMINISTRATION

Recommended Dosage: The recommended dosage of Jaypirca is 200 mg orally once daily until disease progression or unacceptable toxicity. Advise patients of the following:

- Swallow tablets whole with water. Do not cut, crush, or chew tablets.
- Take Jaypirca at the same time each day. Jaypirca may be taken with or without food.
- If a dose of Jaypirca is missed by more than 12 hours, do not make up the dose and take the next dose as scheduled.

Dosage Modifications for Adverse Reactions: Recommended dosage modifications of Jaypirca for adverse reactions are presented in the table below *[see Warnings and Precautions]*.

Recommended Dosage Modification of Jaypirca for Adverse Reactions

Adverse Reaction	Occurrences Requiring Dose Modification	Modification (Starting Dosage: 200 mg once daily)
• Grade 3 or greater non-hematologic toxicity [a] • Absolute neutrophil count < 1 to 0.5 x 10^9/L with fever and/or infection • Absolute neutrophil count < 0.5 x 10^9/L lasting 7 or more days • Platelet count < 50 to 25 x 10^9/L with bleeding • Platelet count < 25 x 10^9/L	**First occurrence**	Interrupt Jaypirca until recovery to Grade 1 or baseline; restart at original dosage (200 mg once daily)[a].
	Second occurrence	Interrupt Jaypirca until recovery to Grade 1 or baseline; restart at 100 mg once daily.
	Third occurrence	Interrupt Jaypirca until recovery to Grade 1 or baseline; restart at 50 mg once daily.
	Fourth occurrence	Discontinue Jaypirca.

Dose modification is not recommended for asymptomatic lymphocytosis. Asymptomatic lipase increase may not necessarily warrant dose modification.

[a] Evaluate the benefit-risk before resuming treatment at the same dose for a Grade 4 non-hematological toxicity.

Dosage Modifications for Patients with Severe Renal Impairment: For patients with severe renal impairment (eGFR 15-29 mL/min), reduce the Jaypirca dose to 100 mg once daily if the current dose is 200 mg once daily otherwise reduce the dose by 50 mg. If the current dosage is 50 mg once daily, discontinue Jaypirca *[see Use in Specific Populations]*. No dosage adjustment of Jaypirca is recommended in patients with mild to moderate renal impairment (eGFR 30-89 mL/min).

Dosage Modifications for Concomitant Use with Strong CYP3A Inhibitors: Avoid concomitant use of strong CYP3A inhibitors with Jaypirca *[see Drug Interactions]*. If concomitant use of a strong CYP3A inhibitor is unavoidable, reduce the Jaypirca dose by 50 mg. If the current dosage is 50 mg once daily, interrupt Jaypirca treatment for the duration of strong CYP3A inhibitor use. After discontinuation of a strong CYP3A inhibitor for 5 half-lives, resume the Jaypirca dose that was taken prior to initiating the strong CYP3A inhibitor.

Dosage Modifications for Concomitant Use with CYP3A Inducers: Avoid concomitant use of strong or moderate CYP3A inducers with Jaypirca *[see Drug Interactions]*. If concomitant use with moderate CYP3A inducers is unavoidable and the current dosage of Jaypirca is 200 mg once daily, increase the dose to 300 mg. If the current dosage is 50 mg or 100 mg once daily, increase the dose by 50 mg.

PATIENT COUNSELING INFORMATION: Advise the patient to read the FDA-approved patient labeling (Patient Information).

Additional information can be found at www.jaypirca.com

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| 2024 |

MEDICAL CONFERENCES

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American Association for Hand Surgery 2024 Annual Meeting
January 9 – 13, 2024
Nassau, Bahamas
978-927-8330
www.handsurgery.org

American Society for Reconstructive Microsurgery Annual Meeting 2024
January 12 – 16, 2024
Miami Nassau, Bahamas
312-456-9579
www.microsurg.org

CANS Annual Meeting 2024
California Association of Neurological Surgeons
January 12 - 14, 2024
San Francisco, CA
916-457-2267
www.cans1.org

SCCM Critical Care Congress
Society of Critical Care Medicine
January 21 – 23, 2024
Phoenix, AZ
847-827-6888
www.sccm.org

STS Annual Meeting
Society of Thoracic Surgeons
January 27 – 29, 2024
San Antonio, TX
312-202-5800
www.sts.org

FEBRUARY

ORS 2024 Annual Meeting
Orthopaedic Research Society
February 2 – 6, 2024
Long Beach, CA
847-823-5770
www.ors.org

Pri-Med South
February 8 – 10, 2024
Ft. Lauderdale, FL
877-477-4633
www.pri-med.com

Biophysical Society Annual Meeting 2024
Biophysical Society
February 10 – 14, 2024
Philadelphia, PA
240-290-5600
www.biophysics.org/2024meeting#/

AAOS Annual Meeting 2024
American Academy of Orthopaedic Surgeons
February 12 –16, 2024
San Francisco, CA
847-823-7186
www.aaos.org

2024 AAAAI Annual Meeting
American Academy of Allergy Asthma & Immunology
February 23 – 26, 2024
Washington, DC
414-272-6071
www.annualmeeting.aaaai.org

MARCH

The Aesthetic Meeting 2024
The American Society for Aesthetic Plastic Surgery
May 2 – 5, 2024
Vancouver, BC
800-364-2147
www.surgery.org

AAD Annual Meeting 2024
American Academy of Dermatology
March 8 – 12, 2024
San Diego, CA
866-503-7546
www.aad.org/meetings/annual-meeting

AORN Global Surgical Conference & Expo 2024
Association of Perioperative Registered Nurses
March 9 – 12, 2024
Nashville, TN
800-755-2676
www.aorn.org

AAPM Annual Meeting
American Academy of Pain Medicine
March 10 – 7, 2024
Scottsdale, AZ
847-375-4731
www.aapmannualmeeting.com

2024 Annual HIMSS Conference & Exhibition
Healthcare Information and Management Systems
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March 16 – 18, 2024
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312-235-4060
www.sgo.org

SSO 2024 Annual Cancer Symposium Society of Surgical Oncology
March 20 – 23, 2024
Atlanta, GA
847-427-1400
www.surgonc.org

SIR 2024 Annual Scientific Meeting Society of Interventional Radiology
March 23 – 28, 2024
Salt Lake City, UT
800-488-7284
www.SIRmeeting.org

APRIL

AACR Annual Meeting 2024 American Association of Cancer Research
April 5 – 10, 2024
San Diego, CA
866-423-3965
www.aacr.org

AAC 2024 Annual Scientific Session and Expo American College of Cardiology
April 6 – 8, 2024
Atlanta, GA
800-253-4636
https://accscientificsession.acc.org

AMGA Annual Conference 2024 American Medical Group Association
April 9 – 12, 2024
Orlando, FL
703-838-0033
www.amga.org

ASBS Annual Meeting 2024 American Society of Breast Surgeons
April 10 – 14, 2024
Orlando, FL
877-992-5470
www.breastsurgeons.org

ASLMS 2024 Annual Conference American Society for Laser Medicine & Surgery
April 11 – 14, 2024
Baltimore, MD
877-258-6028
www.aslms.org

Pri-Med Southwest 2024
April 11 – 13, 2024
Houston, TX
877-774-6338
www.pri-med.com

ACR Annual Meeting 2024 American College of Radiology
April 13 – 17, 2024
Washington, DC
800-243-7419
www.acr.org/annual-meeting

ARRS Annual Meeting 2024 American Roentgen Ray Society
April 13 – 18, 2024
Denver, CO
866-940-2777
www.arrs.org

SAGES 2024 Annual Meeting Society of American Gastrointestinal Endoscopic Surgeons
April 17 – 20, 2024
Cleveland, OH
310-437-0544
www.sages2024.surgery

ACP Internal Medicine Meeting 2024 American College of Physicians
April 18 – 20, 2024
Boston, MA
800-523-1546
https://annualmeeting.acponline.org/

AAN Annual Meeting 2024 American Academy of Neurology
April 22 – 27, 2024
Boston, MA
800-879-1960
www.aan.com

AATS Annual Meeting 2024 American Association for Thoracic Surgery
April 27 – 30, 2024
Toronto, ON
978-927-8330
www.aats.org

MAY

AANS Annual Scientific Meeting 2024 American Association of Neurological Surgeons
May 3 – 6, 2024
Chicago, CA
847-378-0500
www.aans.org

AACE 2024 Annual Scientific & Clinical Congress American Association of Clinical Endocrinologists
May 9 – 11, 2024
New Orleans, LA
904-353-7878
www.aace.com

AANA Annual Congress 2024 Arthroscopy Association of North America
May 9 – 11 2024
Boston, MA
847-292-2262
www.aana.org

ACOG 2024 Annual Clinical and Scientific Meeting American College of Obstetricians and Gynecologists
May 17 – 19, 2024
San Francisco, CA
800- 673-8444
www.acog.org

ATS 2024 International Conference American Thoracic Society
May 17 – 22, 2024
San Diego, CA
212-315-8600
conference.thoracic.org

ASNR Annual Meeting & The Foundation of the ASNR Symposium 2024 American Society of Neuroradiology
May 18 – 22, 2024
Las Vegas, NV
630-574-0220
www.asnr.org

ACSM Annual Meeting
American College of Sports Medicine
May 28 – 21, 2024
Boston, MA
317-637-9200
www.acsm.org/annual-meeting/annual-home

JUNE

APIC Annual Conference 2024
Association for Professional in Infection Control and Epidemiology
June 3 – 5, 2024
San Antonio, TX
202-789-1890
annual.apic.org

BIO International Convention 2024
Biotechnology Industry Organization
June 3 – 6, 2024
San Diego, CA
202-962-6655
bio.org/

SNMMI 2024 Annual Meeting
Society of Nuclear Medicine & Molecular Imaging
June 8 – 10, 2024
Toronto, ON
703-708-9000
www.snmmi.org

AMA Annual Meeting of House of Delegates 2024
American Medical Association
June 8 – 12, 2024
Chicago, Illinois
800-621-8335
www.ama-assn.org

ENDO Annual Meeting 2024
The Endocrine Society
June 11 – 14, 2024
Atlanta, GA
888-363-6274
www.endocrine.org

JULY

Pri-Med West 2024
July 18 – 20, 2024
Anaheim, CA
877-774-6338
www.pri-med.com

AAPM Annual Meeting 2024
American Association of Physicists in Medicine
July 21 – 25, 2024
Los Angeles, CA
571-298-1300
www.aapm.org

ADLM 2024 Annual Meeting & Clinical Lab Expo
(Formerly AACC)
Association for Diagnostics & Laboratory Medicine
July 28 – August 1, 2024
Chicago, IL
800-892-1400
www.aacc.org

AUGUST

PDA Annual Meeting
Pacific Dermatologic Association
August 22 – 25, 2024
Huntington Beach, CA
888-388-8815
www.pacificderm.org

SEPTEMBER

FMX 2024
American Academy of Family Physicians
September 24 – 28, 2024
Phoenix, AZ
800-274-2237
www.aafp.org

NASS 2024 Annual Meeting
North American Spine Society
September 25 – 28, 2024
Chicago, IL
630-230-3600
www.spine.org

CNS Annual Meeting 2024
Congress of Neurological Surgeons
September 28 – October 2, 2024
Houston, TX
847-240-2500
www.cns.org

ACEP Annual Scientific Assembly 2024
American College of Emergency Physicians
September 29 – October 2, 2024
Las Vegas, NV
800-798-1822
www.acep.org

ASTRO Annual Meeting 2024
American Society for Therapeutic Radiology & Oncology
September 29 – October 2, 2024
Washington, DC
703-502-1550
www.astro.org

OCTOBER

CHEST 2024 ACCP Annual Meeting
American College of Chest Physicians
October 6 –9, 2024
Boston, MA
800-343-2227
www.chestnet.org

ISPE Annual Meeting 2024
International Society for Pharmaceutical Engineering
October 13 – 16, 2024
Orlando, FL
301-364-9201
www.ispe.org

AAO Annual Meeting 2024
American Academy of Ophthalmology
October 18 – 21, 2024
Chicago, IL
415-561-8500
www.aao.org

The ANESTHESIOLOGY 2024 Annual Meeting
American Society of Anesthesiologists
October 18 – 22, 2024
Philadelphia, PA
847-825-5586
www.asahq.org

ASRM Scientific Congress and Expo 2024
American Society for Reproductive Medicine
October 19 – 23, 2024
Denver, CO
205-978-5000
www.asrm.org

ACAAI 2024 Annual Meeting
American College of Allergy Asthma & Immunology
October 24 – 28, 2024
Boston, MA
847-427-1200
www.acaai.org

NOVEMBER

ASHG 2024
American Society of Human Genetics
November 5 – 9, 2024
Denver, CO
301-634-7300
www.ashg.org

DECEMBER

RSNA 2024
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Radiological Society of North America
December 1 – 5, 2024
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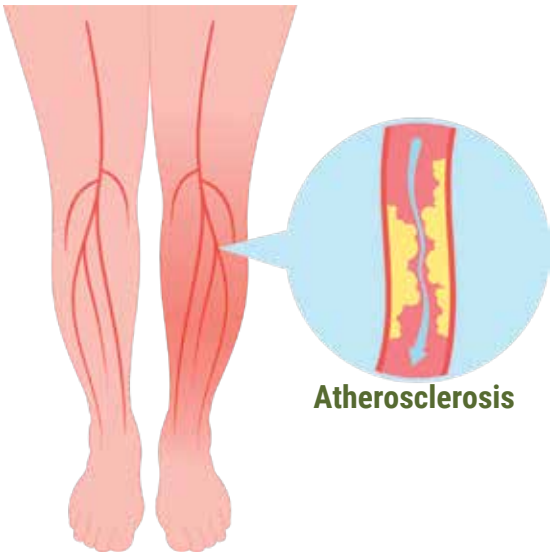
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Micro Direct, Inc.
www.mdspiro.com

Midmark Diagnostics, Inc.
www.midmark.com

MIR – Medical International Research
www.spirometry.com

Nasiff Associates, Inc.
www.nasiff.com

ndd Medical Technologies
www.nddmed.com

Nihon Kohden
www.nohonkohden.com

Nonin Medical
www.nonin.com

Schiller America, Inc.
www.schillerus.com

SDI Diagnostics Inc.
www.sdidiagnostics.com

Vitalograph
www.vitalograph.com

Welch Allyn
www.welchallyn.com

CENTRIFUGES
Drucker Diagnostics
www.druckerdiagnostics.com

CHEMISTRY ANALYZERS
Abbott Diagnostics
www.corelaboratory.abbott

Abbott Point of Care
www.globalpointofcare.abbott

AMS Diagnostics
www.amsdiagnostics.com

Beckman Coulter
www.beckmancoulter.com

Arkray
www.arkrayusa.com

Carolina Liquid Chemistries, Inc.
www.carolinachemistries.com

ELITech Group
www.elitechgroup.com

Horiba Medical
www.horiba.com/us/en/medical

Jant Pharmacal
www.accutest.net

Medica Corporation
www.medicacorp.com

Randox Laboratories, USA
www.randox.com

Roche
www.roche.com

Sekisui
www.sekisuidiagnostics.com

Vital Diagnostics
www.vitaldiagnostics.com

CHOLESTEROL & TRIGLYCERIDE TESTING

Abbott
www.globalpointofcare.abbott

Alfa Wassermann, Inc
www.alfawassermannus.com

Arkray
www.arkrayusa.com

Beckman Coulter, Inc.
www.beckman.com

Carolina Liquid Chemistries, Inc.
www.carolinachemistries.com

Horiba Medical
www.horiba.com/us/en/medical

Medica Corporation
www.medicacorp.com

PTS Diagnostics
www.ptsdiagnostics.com

Randox Laboratories, Inc.
www.randox.com

COAGULATION

Roche
www.roche.com

CONJUNCTIVITIS TESTS

RPS Diagnostics
www.rpsdetectors.com

COVID-19 TESTS

BD
https://bdveritor.bd.com/en-us

bioMerieux
www.biomerieux.com

LumiraDx
www.lumiradx.com

Mercedes Scientific
www.mercedesscientific.com

Quidel
www.quidel.com

Sekisui
www.sekisui.com

CREATININE

Siemens Healthcare Diagnostics
www.siemens-healthineers.com

CRYOSURGICAL DEVICES

CryoProbe
www.ho-equipments.com

CryoConcepts, LP
www.cryoconcepts.com

DIABETES

Abbott
www.globalpointofcare.abbott

Semler Scientific
www.semlerscientific.com

Siemens Healthcare Diagnostics
www.siemens-healthineers.com

DEFIBRILLATORS

Medical Device Depot
www.medicaldevicedepot.com

Zoll
www.zoll.com
DOPPLERS

Huntleigh Diagnostics
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Medical Device Depot
www.medicaldevicedepot.com

Newman Medical
www.newman-medical.com

Wallach Surgical Devices
www.wallachsurgical.com

DRUGS OF ABUSE TESTS

Carolina Liquid Chemistries
www.carolinachemistries.com

Horiba
www.horiba.com/us/en/medical

Laboratory Consulting, LLC
www.urinedrugscreenconsulting.com

Randox Laboratories, Inc.
www.randox.com

Sekisui
www.sekisuidiagnostics.com

EAR, NOSE & THROAT

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www.bionix.com

Brilliant Medical
www.brilliantmedical.com

HEINE Optotechnik
www.heine.com

Med-Electronics, Inc.
www.med-electronics.com

Welch Allyn, Inc.
www.welchallyn.com

ECG

Edan Diagnostics
www.edandiagnostics.com

GE Healthcare Technologies
www.gehealthcare.com

Medical Device Depot
www.medicaldevicedepot.com

Midmark Diagnostics, Inc.
www.midmark.com

Mortara
www.mortara.com

Schiller America, Inc.
www.schilleramerica.com

Vitalograph
www.vitalograph.com

Welch Allyn
www.welchallyn.com

EDUCATION

AAFP
www.aafp.org

COLA
www.cola.org

ELECTROLYTE

Abbott Point of Care
www.globalpointofcare.abbott

Medica Corporation
www.medicacorp.com

OPTI MEDICAL SYSTEMS, INC.

Roche
www.roche.com

PRODUCT CATEGORIES

ENDOSCOPY
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www.pentaxmedical.com

E-PRESCRIBING
Amazing Charts
www.amazingcharts.com

DrFirst
www.drfirst.com

ESR
ALCOR Scientific
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EXAM ROOM FURNITURE
Brewer Medical
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www.clinicalgenomics.com

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www.hemosure.com

Jant Pharmacal
www.accutest.net

Sekisui
www.sekisui.com

FLU TESTING
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https://bdveritor.bd.com/en-us

bioMerieux
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Cepheid
www.cepheid.com

Quidel
www.quidel.com

Roche
www.Roche.com

Sekisui
www.sekisuidiagnostics.com

GASTROINTESTINAL DISEASE TESTING
bioMerieux
www.biofiredx.com

GLUCOSE TESTING
Abbott Point of Care
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Abbott Rapid Diagnostics
www.globalpointofcare.abbott

Hemocue, Inc.
www.hemocue.com

Jant Pharmacal
www.jantdx.com

Nova Biomedical
www.novabiomedical.com

Roche
go.roche.com/rochelancets

H. PYLORI
Sekisui
www.sekisuidiagnostics.com

HCV – HIV TESTING
Orasure
www.orasure.com

HEART DYSFUNCTION
Semler Scientific
www.semlerscientific.com

HEMATOLOGY ANALYZERS

Abbott
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ALCOR Scientific
www.alcorescientific.com

Beckman Coulter, Inc.
www.beckmancoulter.com

Drucker Diagnostics, Inc.
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Hemocue, Inc.
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Horiba Medical
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Jant Pharmacal
www.accutest.net

Sysmex America, Inc.
www.sysmex.com/us

HEMOGLOBIN ANALYZERS
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EKF DIAGNOSTICS
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www.hemocue.com

Masimo Corporation
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IMMUNOASSAY INSTRUMENTS
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Beckman Coulter, Inc.
www.beckmancoulter.com

NanoEnTek
www.nanoentek.com

Sekisui Diagnostics
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INFECTIOUS DISEASE
bioMerieux
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Roche
www.roche.com

Sekisui
www.sekisui.com

LABORATORY INFORMATION SYSTEMS

Alfa Wassermann, Inc

Jant Pharmacal
www.accutest.net

Medicus LIS
www.medicuslis.com

Orchard Software
www.orchardsoft.com

LABORATORY SANATIZERS

Clorox

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LAB SERVICES
AAFP
www.aafp.org

COLA
www.cola.org

COLA Resources Inc.
www.criedu.org

Medicus Middleware
www.medicusmiddleware.com

My Inspection
http://myinspection.us

LANCETS
Roche
go.roche.com/rochelancets

LEAD TESTING
Meridian Bioscience
www.magellandx.com

LIPID TESTING
Abbott Rapid Diagnostics
www.globalpointofcare.abbott

METABOLIC TESTING
Korr Medical Technologies, Inc.
www.korr.com

MOBILE HEALTH TECHNOLOGY
Medpod
www.medpodhealth.com

MONITORS
Edan Diagnostics
www.edandiagnostics.com

GE Healthcare Technologies
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Medical Device Depot
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Midmark
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Welch Allyn
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NEUROLOGICAL TESTING
Advanced Clinical Products
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Brilliant Medical
www.brilliantmedical.com

Evoke Neuroscience
www.evokeneuroscience.com

Morningside Medical Equipment
www.morningsidemedicalequipment.com

PAIN PRACTICE LAB
Mercedes Medical
www.mercedesmedical.com

PERIPHERAL ARTERY DISEASE (PAD)
Semler Scientific
www.semlerscientific.com

PHOTOTHERAPY SOLUTIONS
Daavlin Company
www.daavlin.com

PRACTICE MANAGEMENT
Athena Health
www.athenahealth.com

ZirMed
www.zirmed.com

PT/INR
Roche
www.Roche.com

PULSE OXIMETERS
Masimo Corporation
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REAGENTS
Abbott Diagnostics
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Beckman Coulter
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RESPIRATORY INFECTIONS
BD
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bioMerieux
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Cepheid
www.cepheid.com
LumiraDx
www.lumiradx.com

Quidel
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Roche
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SLEEP DISORDERS
ResMed
www.resmed.com

SPIROMETRY
Futuremed America, Inc.
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Medical Device Depot
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Micro Direct, Inc.
www.mdspiro.com

Midmark Diagnostics, Inc.
www.midmark.com

MIR – Medical International Research
www.spirometry.com

ndd Medical Technologies
www.nddmed.com

Vitalograph
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Welch Allyn
www.welchallyn.com

STREP TESTING
Alere, Inc.
www.alere.com

BD
https://bdveritor.bd.com/en-us

Cepheid
www.cepheid.com

Beckman Coulter, Inc.
www.beckmancoulter.com
LifeSign, LLC
www.lifesignmed.com

Quidel
www.quidel.com

Roche
www.roche.com

Sekisui
www.sekisuidiagnostics.com

SYNDROMIC TESTING
bioMerieux
www.BioFireDx.com

TELEHEALTH
Medpod
www.medpodhealth.com

THERMOMETERS
Exergen Corporation
www.exergen.com

TOXICOLOGY
Abbott Clinical Laboratory Solutions
www.diagnostics.abbott.com

Mercedes Medical
www.mercedesmedical.com

ULTRASOUND
Interson
www.interson.com

Samsung Medison
www.samsungmedison.com

URINALYSIS
Abbott Rapid Diagnostics
www.globalpointofcare.abbott

Jant Pharmacal
www.accutest.net

LifeSign, LLC
www.lifesignmed.com

Roche
www.roche.com

Siemens Healthcare Diagnostics
www.siemens-healthineers.com

WOMEN'S HEALTH

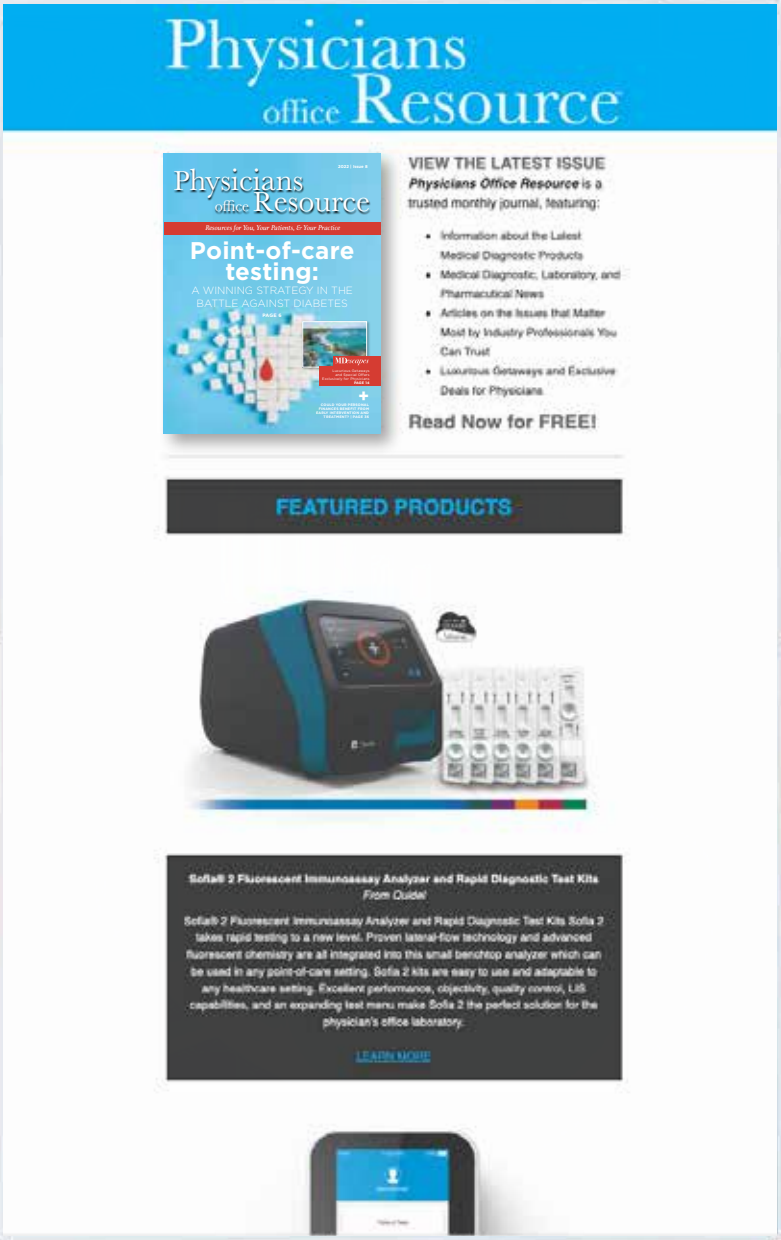
Sekisui Diagnostics
www.sekisuidiagnostics.com

WEIGHT MANAGEMENT
Korr Medical Technologies, Inc.
www.korr.com

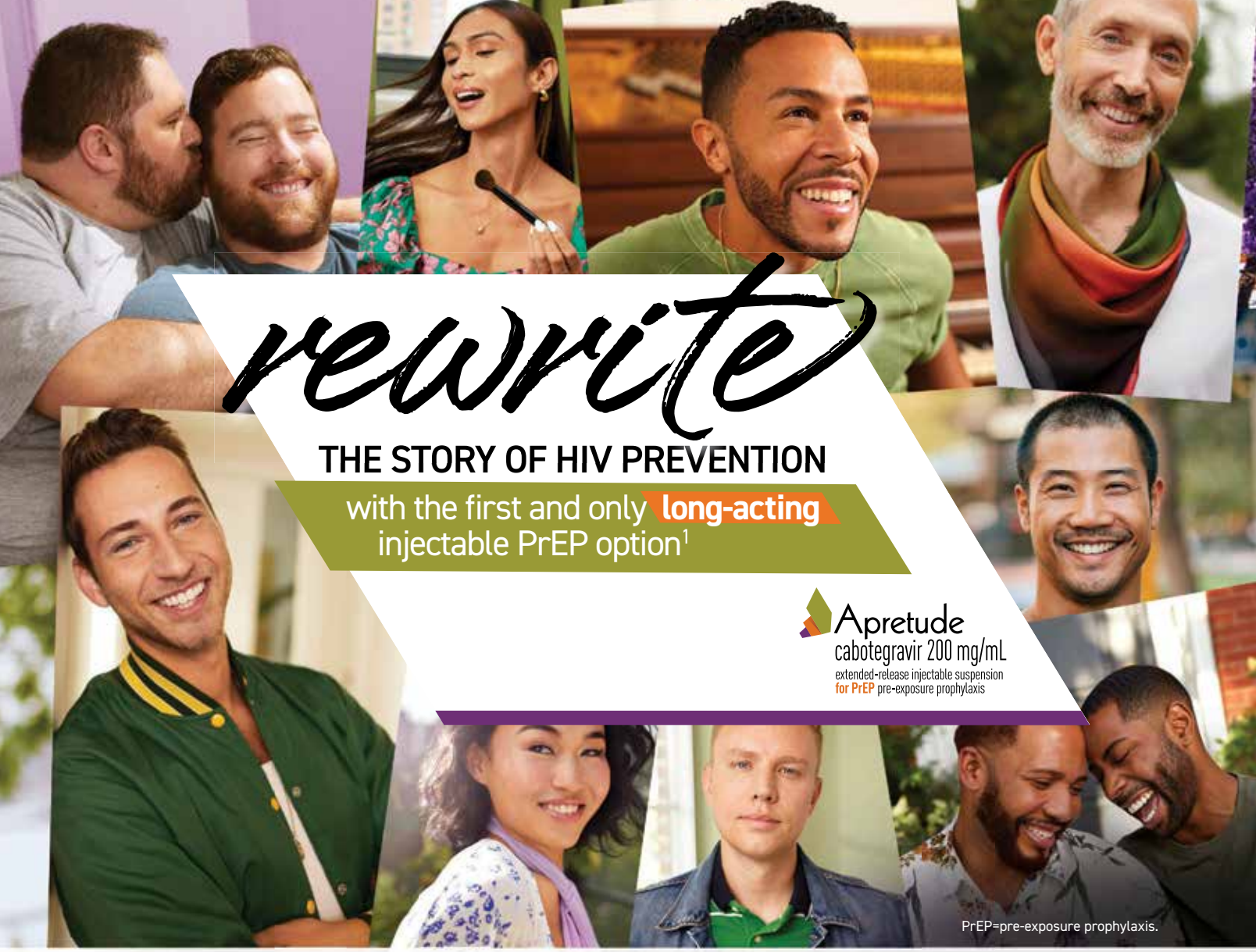
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APRETUDE is administered as an intramuscular injection by a healthcare professional every 2 months after 2 initiation injections administered 1 month apart.

INDICATION

APRETUDE is indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test prior to initiating APRETUDE (with or without an oral lead-in with oral cabotegravir) for HIV-1 PrEP.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: RISK OF DRUG RESISTANCE WITH USE OF APRETUDE FOR HIV-1 PRE-EXPOSURE PROPHYLAXIS (PrEP) IN UNDIAGNOSED HIV-1 INFECTION

Individuals must be tested for HIV-1 infection prior to initiating APRETUDE or oral cabotegravir, and with each subsequent injection of APRETUDE, using a test approved or cleared by the FDA for the diagnosis of acute or primary HIV-1 infection. Drug-resistant HIV-1 variants have been identified with use of APRETUDE by individuals with undiagnosed HIV-1 infection. Do not initiate APRETUDE for HIV-1 PrEP unless negative infection status is confirmed. Individuals who become infected with HIV-1 while receiving APRETUDE for PrEP must transition to a complete HIV-1 treatment regimen.

Please see following pages for additional Important Safety Information.
Please see following pages for Brief Summary of full Prescribing Information, including Boxed Warning, for APRETUDE.

Apretude
cabotegravir 200 mg/mL
extended-release injectable suspension
for PrEP pre-exposure prophylaxis

Only with APRETUDE:

SUPERIOR efficacy proven in 2 trials and the CONFIDENCE that comes from adherence you can confirm in office[1]

SUPERIOR:

Provided greater protection from HIV than a daily oral PrEP (TDF/FTC)

Significantly lower incidence of HIV-1 infection—69% (12* vs 39 [*P*=0.0003]) and 90% (3† vs 36 [*P*<0.0001])—vs a daily oral PrEP demonstrated in HPTN 083 and HPTN 084[1-3‡§]

- Of the incident and prevalent infections in the APRETUDE arm, INSTI resistance-associated mutations (RAMs) were detected in 4 and 1 participant(s), respectively, in HPTN 083,[1,4] and no major RAMs were detected in HPTN 084[1]
- Of the incident and prevalent infections in the TDF/FTC arm, NRTI RAMs were detected in 4 and 2 participants, respectively, in HPTN 083,[4] and 1 incident infection with an NRTI RAM was detected in HPTN 084[5]

CONFIDENT:

Every-2-month dosing means no more daily PrEP pills‖

Adherence you can confirm with as few as 6 in-office injections per year[1¶]

- See additional dosing and HIV-1 testing information at APRETUDEHCP.com

Would your patients benefit from a switch to long-acting APRETUDE?

Learn more about APRETUDE at **APRETUDEHCP.com**

*In HPTN 083, the primary analysis showed a 66% reduction in the risk of acquiring HIV-1 infection (hazard ratio [95% CI]: 0.34 [0.18-0.62]). Further testing revealed 1 of the infections on APRETUDE to be prevalent, yielding a 69% reduction in the risk of incident HIV-1 infection relative to TDF/FTC (hazard ratio [95% CI]: 0.31 [0.16-0.58]); incidence rate was 0.37/100 person-years for APRETUDE vs 1.22/100 person-years for TDF/FTC.[1]

†In HPTN 084, the primary analysis showed an 88% reduction in the risk of acquiring HIV-1 infection (hazard ratio [95% CI]: 0.12 [0.05-0.31]). Further testing revealed 1 of the infections on APRETUDE to be prevalent, yielding a 90% reduction in the risk of incident HIV-1 infection relative to TDF/FTC (hazard ratio [95% CI]: 0.10 [0.04-0.27]); incidence rate was 0.15/100 person-years for APRETUDE vs 1.85/100 person-years for TDF/FTC.[1]

‡HPTN 083 (N=4566) was a randomized, double-blind, placebo-controlled noninferiority trial of the safety and efficacy of APRETUDE compared with daily oral TDF/FTC for HIV-1 prevention in HIV-1–uninfected men and transgender women who have sex with men and have evidence of high-risk behavior for HIV-1 infection. The primary endpoint was the rate of incident HIV-1 infections among participants randomized to daily oral cabotegravir for up to 5 weeks followed by intramuscular injections of APRETUDE every 2 months compared with daily oral TDF/FTC (corrected for early stopping). The trial included the prespecified ability to test for superiority of APRETUDE over TDF/FTC.[1,2]

§HPTN 084 (N=3224) was a randomized, double-blind, placebo-controlled superiority trial of the safety and efficacy of APRETUDE compared with daily oral TDF/FTC for HIV-1 prevention in adult, uninfected cisgender women at risk of acquiring HIV-1. The primary endpoint was the rate of incident HIV-1 infections among participants randomized to daily oral cabotegravir for up to 5 weeks followed by injections of APRETUDE compared with oral TDF/FTC (corrected for early stopping).[1,3]

‖While on APRETUDE.

¶After initiation injections.[1]

IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS

- Do not use APRETUDE in individuals:
  - with unknown or positive HIV-1 status
  - with previous hypersensitivity reaction to cabotegravir
  - receiving carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, and rifapentine

Please see following pages for additional Important Safety Information.
Please see following pages for Brief Summary of full Prescribing Information, including Boxed Warning, for APRETUDE.



INCLUSIVE:

Evaluated across a diverse population

The most diverse and comprehensive participant population in HIV prevention trials conducted to date[1-3‡§]

- Designed to include key populations at risk for HIV-1: Trials included HIV-1–negative cisgender men and transgender women who have sex with men and cisgender women, with the majority under age 30[1-3,6]
- In the US, HPTN 083 was inclusive of the Black/African American and Latinx communities who comprise the greatest percentage of new HIV diagnoses[1,2,7]

SAFETY PROFILE[1]:

Demonstrated in ~4000 participants

- The most common adverse reactions (all grades) observed in at least 1% of subjects receiving APRETUDE were ISRs, diarrhea, headache, pyrexia, fatigue, sleep disorders, nausea, dizziness, flatulence, abdominal pain, vomiting, myalgia, rash, decreased appetite, somnolence, back pain, and upper respiratory tract infection
  - In HPTN 083, 82% of participants who received APRETUDE experienced at least 1 ISR; 97% were Grade 1 or 2, with 3% of participants experiencing Grade 3 and no Grade 4 reactions reported
  - In HPTN 084, 38% of participants who received APRETUDE experienced at least 1 ISR; >99% were Grade 1 or 2, with <1% of participants experiencing Grade 3 and no Grade 4 reactions reported
- 6% of participants receiving APRETUDE and 4% receiving TDF/FTC in HPTN 083, and 1% of participants in both arms of HPTN 084, discontinued due to adverse events (all causality)

CI=confidence interval; HPTN=HIV Prevention Trials Network; INSTI=integrase strand transfer inhibitor; ISR=injection-site reaction; NRTI=nucleoside/nucleotide reverse transcriptase inhibitor; PrEP=pre-exposure prophylaxis; TDF/FTC=tenofovir disoproxil fumarate/emtricitabine.





IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Comprehensive Management to Reduce the Risk of HIV-1 Infection:

- Use APRETUDE as part of a comprehensive prevention strategy, including adherence to the administration schedule and safer sex practices, including condoms, to reduce the risk of sexually transmitted infections (STIs). APRETUDE is not always effective in preventing HIV-1 acquisition. Risk for HIV-1 acquisition includes, but is not limited to, condomless sex, past or current STIs, self-identified HIV risk, having sexual partners of unknown HIV-1 viremic status, or sexual activity in a high prevalence area or network. Inform, counsel, and support individuals on the use of other prevention measures (e.g., consistent and correct condom use; knowledge of partner(s) HIV-1 status, including viral suppression status; regular testing for STIs)
- Use APRETUDE only in individuals confirmed to be HIV-1 negative. HIV-1 resistance substitutions may emerge in individuals with undiagnosed HIV-1 infection who are taking only APRETUDE, because APRETUDE alone does not constitute a complete regimen for HIV-1 treatment. Prior to initiating APRETUDE, ask seronegative individuals about recent (in past month) potential exposure events and evaluate for current or recent signs or symptoms consistent with acute HIV-1 infection (e.g., fever, fatigue, myalgia, skin rash). If recent (<1 month) exposures to HIV-1 are suspected or clinical symptoms consistent with acute HIV-1 infection are present, use a test approved or cleared by the FDA as an aid in the diagnosis of acute HIV-1 infection

Apretude
cabotegravir 200 mg/mL
extended-release injectable suspension
for PrEP pre-exposure prophylaxis

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Comprehensive Management to Reduce the Risk of HIV-1 Infection: (cont'd)

- When using APRETUDE, HIV-1 testing should be repeated prior to each injection and upon diagnosis of any other STIs
- If an HIV-1 test indicates possible HIV-1 infection, or if symptoms consistent with acute HIV-1 infection develop following an exposure event, additional HIV testing to determine HIV status is needed. If HIV-1 infection is confirmed, then transition the individual to a complete HIV-1 treatment
- Counsel HIV-1 uninfected individuals to strictly adhere to the recommended dosing and testing schedule for APRETUDE

Potential Risk of Resistance with APRETUDE:

- There is a potential risk of developing resistance to APRETUDE if an individual acquires HIV-1 either before, while taking, or following discontinuation of APRETUDE. To minimize this risk, it is essential to clinically reassess individuals for risk of HIV-1 acquisition and to test before each injection to confirm HIV-1–negative status. Individuals who are confirmed to have HIV-1 infection must transition to a complete HIV-1 treatment. Alternative forms of PrEP should be considered following discontinuation of APRETUDE for those individuals at continuing risk of HIV-1 acquisition and initiated within 2 months of the final injection of APRETUDE

Long-Acting Properties and Potential Associated Risks with APRETUDE:

- Residual concentrations of cabotegravir may remain in the systemic circulation of individuals for prolonged periods (up to 12 months or longer). Take the prolonged-release characteristics of cabotegravir into consideration and carefully select individuals who agree to the required every-2-month injection dosing schedule because non-adherence to every-2-month injections or missed doses could lead to HIV-1 acquisition and development of resistance

Hypersensitivity Reactions:

- Serious or severe hypersensitivity reactions have been reported in association with other integrase inhibitors and could occur with APRETUDE
- Discontinue APRETUDE immediately if signs or symptoms of hypersensitivity reactions develop. Clinical status, including liver transaminases, should be monitored and appropriate therapy initiated

Hepatotoxicity:

- Hepatotoxicity has been reported in a limited number of individuals receiving cabotegravir with or without known pre-existing hepatic disease or identifiable risk factors
- Clinical and laboratory monitoring should be considered and APRETUDE should be discontinued if hepatotoxicity is suspected and individuals managed as clinically indicated

Talk to your patients about long-acting HIV prevention with APRETUDE

Learn more at **APRETUDEHCP.com**

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CBTJRNA230005 May 2023

Produced in USA.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Depressive Disorders:

- Depressive disorders (including depression, depressed mood, major depression, persistent depressive disorder, suicidal ideation or attempt) have been reported with APRETUDE
- Promptly evaluate patients with depressive symptoms

Risk of Reduced Drug Concentration of APRETUDE Due to Drug Interactions:

- The concomitant use of APRETUDE and other drugs may result in reduced drug concentration of APRETUDE
- Refer to the full Prescribing Information for steps to prevent or manage these possible and known significant drug interactions, including dosing recommendations. Consider the potential for drug interactions prior to and during use of, and after discontinuation of APRETUDE; review concomitant medications during use of APRETUDE

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥1%, all grades) with APRETUDE were injection site reactions, diarrhea, headache, pyrexia, fatigue, sleep disorders, nausea, dizziness, flatulence, abdominal pain, vomiting, myalgia, rash, decreased appetite, somnolence, back pain, and upper respiratory tract infection.

DRUG INTERACTIONS

- Refer to the full Prescribing Information for important drug interactions with APRETUDE
- Drugs that induce UGT1A1 may significantly decrease the plasma concentrations of cabotegravir

USE IN SPECIFIC POPULATIONS

- **Lactation:** Assess the benefit-risk of using APRETUDE to the infant while breastfeeding due to the potential for adverse reactions and residual concentrations in the systemic circulation for up to 12 months or longer after discontinuation
- **Pediatrics:** Not recommended in individuals weighing less than 35 kg

Please see following pages for Brief Summary of full Prescribing Information, including Boxed Warning, for APRETUDE.

References: 1. APRETUDE [package insert]. Research Triangle Park, NC: ViiV Healthcare; 2021. **2.** Landovitz RJ, Donnell D, Clement ME, et al; HPTN 083 Study Team. Cabotegravir for HIV prevention in cisgender men and transgender women. *N Engl J Med*. 2021;385:595-608. doi:10.1056/NEJMoa2101016 **3.** Delany-Moretlwe S; HPTN 084 Study Team. Long acting injectable cabotegravir is safe and effective in preventing HIV infection in cisgender women: results from HPTN 084. Presented at: HIV R4P Virtual Conference; January 27, 2021. Abstract LB1479. **4.** Marzinke MA, Grinsztejn B, Fogel JM, et al. Characterization of human immunodeficiency virus (HIV) infection in cisgender men and transgender women who have sex with men receiving injectable cabotegravir for HIV prevention: HPTN 083. *J Infect Dis*. 2021;224(9):1581-1592. doi:10.1093/infdis/jiab152 **5.** Marzinke MA, Delany-Moretlwe S, Agyei Y; HPTN 084 Study Team. Long-acting injectable PrEP in women: laboratory analysis of HIV infections in HPTN 084. Poster presented at: 11th International AIDS Society Conference on HIV Science; July 18-21, 2021. **6.** HIV in the United States and dependent areas. Centers for Disease Control and Prevention. Updated August 9, 2021. Accessed March 11, 2022. https://www.cdc.gov/hiv/statistics/overview/ataglance.html **7.** Centers for Disease Control and Prevention. *HIV Surveillance Report, 2019*. Vol 32. May 2021. https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-32/index.html

Apretude
cabotegravir 200 mg/mL
extended-release injectable suspension
for PrEP pre-exposure prophylaxis

BRIEF SUMMARY

APRETUDE (cabotegravir extended-release injectable suspension), for intramuscular use

The following is a brief summary only; see full Prescribing Information, including Boxed Warning, for complete product information.

WARNING: RISK OF DRUG RESISTANCE WITH USE OF APRETUDE FOR HIV-1 PRE-EXPOSURE PROPHYLAXIS (PrEP) IN UNDIAGNOSED HIV-1 INFECTION

Individuals must be tested for HIV-1 infection prior to initiating APRETUDE or oral cabotegravir, and with each subsequent injection of APRETUDE, using a test approved or cleared by the FDA for the diagnosis of acute or primary HIV-1 infection. Drug-resistant HIV-1 variants have been identified with use of APRETUDE by individuals with undiagnosed HIV-1 infection. Do not initiate APRETUDE for HIV-1 PrEP unless negative infection status is confirmed. Individuals who become infected with HIV-1 while receiving APRETUDE for PrEP must transition to a complete HIV-1 treatment regimen.

CONTRAINDICATIONS

APRETUDE is contraindicated in individuals: with unknown or positive HIV-1 status; with previous hypersensitivity reaction to cabotegravir; receiving the following coadministered drugs for which significant decreases in cabotegravir plasma concentrations may occur due to uridine diphosphate glucuronosyltransferase (UGT)1A1 enzyme induction, which may result in reduced effectiveness–Anticonvulsants: carbamazepine, oxcarbazepine, phenobarbital, phenytoin; Antimycobacterials: rifampin, rifapentine.

WARNINGS AND PRECAUTIONS

Comprehensive Management to Reduce the Risk of HIV-1 Infection: Use APRETUDE for HIV-1 PrEP to reduce the risk of HIV-1 infection as part of a comprehensive prevention strategy including adherence to the administration schedule and safer sex practices, including condoms, to reduce the risk of sexually transmitted infections (STIs). APRETUDE is not always effective in preventing HIV-1 acquisition. The time from initiation of APRETUDE for HIV-1 PrEP to maximal protection against HIV-1 infection is unknown. Risk for HIV-1 acquisition includes behavioral, biological, or epidemiologic factors including, but not limited to, condomless sex, past or current STIs, self-identified HIV risk, having sexual partners of unknown HIV-1 viremic status, or sexual activity in a high prevalence area or network. Counsel individuals on the use of other prevention measures (e.g., consistent and correct condom use; knowledge of partner(s)' HIV-1 status, including viral suppression status; regular testing for STIs that can facilitate HIV-1 transmission). Inform individuals about and support their efforts in reducing sexual risk behavior. Use APRETUDE to reduce the risk of acquiring HIV-1 only in individuals confirmed to be HIV-1 negative. HIV-1 resistance substitutions may emerge in individuals with undiagnosed HIV-1 infection who are taking only APRETUDE, because APRETUDE alone does not constitute a complete regimen for HIV-1 treatment; therefore, care should be taken to minimize the risk of initiating or continuing APRETUDE before confirming the individual is HIV-1 negative. Prior to initiating APRETUDE for HIV-1 PrEP, ask seronegative individuals about recent (in past month) potential exposure events (e.g., condomless sex or condom breaking during sex with a partner of unknown HIV-1 status or unknown viremic status, a recent STI), and evaluate for current or recent signs or symptoms consistent with acute HIV-1 infection (e.g., fever, fatigue, myalgia, skin rash). If recent (<1 month) exposures to HIV-1 are suspected or clinical symptoms consistent with acute HIV-1 infection are present, use a test approved or cleared by the FDA as an aid in the diagnosis of acute or primary HIV-1 infection. When using APRETUDE for HIV-1 PrEP, HIV-1 testing should be repeated prior to each injection and upon diagnosis of any other STIs. If an HIV-1 test indicates possible HIV-1 infection, or if symptoms consistent with acute HIV-1 infection develop following an exposure event, additional HIV testing to determine HIV status is needed. If an individual has confirmed HIV-1 infection, then the individual must be transitioned to a complete HIV-1 treatment regimen. Counsel HIV-1–uninfected individuals to strictly adhere to the recommended dosing and testing schedule for APRETUDE in order to reduce the risk of HIV-1 acquisition and the potential development of resistance. Some individuals, such as adolescents, may benefit from frequent visits and counseling to support adherence to the dosing and testing schedule. **Potential Risk of Resistance with APRETUDE:** There is a potential risk of developing resistance to APRETUDE if an individual acquires HIV-1 either before or while taking APRETUDE or following discontinuation of APRETUDE. To minimize this risk, it is essential to clinically reassess individuals for risk of HIV-1 acquisition and to test before each injection to confirm HIV-1 negative status. Individuals who are confirmed to have HIV-1 infection must transition to a complete HIV-1 treatment regimen. Alternative forms of PrEP should be considered following discontinuation of APRETUDE for those individuals at continuing risk of HIV-1 acquisition and initiated within 2 months of the final injection of APRETUDE. **Long-Acting Properties and Potential Associated Risks with APRETUDE:** Residual concentrations of cabotegravir may remain in the systemic circulation of individuals for prolonged periods (up to 12 months or longer). It is important to carefully select individuals who agree to the required every-2-month injection dosing schedule because non-adherence to every-2-monthly injections or missed doses could lead to HIV-1 acquisition and development of resistance. Healthcare providers should take the prolonged-release characteristics of cabotegravir into consideration when APRETUDE is prescribed. **Hypersensitivity Reactions:** Serious or severe hypersensitivity reactions have been reported in association with other integrase inhibitors and could occur with APRETUDE. Administration of cabotegravir oral lead-in dosing was used in clinical studies to help identify participants who may be at risk of a hypersensitivity reaction. Remain vigilant and discontinue APRETUDE if a hypersensitivity reaction is suspected. Discontinue APRETUDE immediately if signs or symptoms of hypersensitivity reactions develop (including, but not limited to, severe rash, or rash accompanied by fever, general malaise, fatigue, muscle or joint aches, blisters, mucosal involvement [oral blisters or lesions], conjunctivitis, facial edema, hepatitis, eosinophilia, angioedema, difficulty breathing). Clinical status, including liver transaminases, should be monitored and appropriate therapy initiated. For information regarding the long-acting properties of APRETUDE, see previous section. **Hepatotoxicity:** Hepatotoxicity has been reported in a limited number of individuals receiving cabotegravir with or without known pre-existing hepatic disease or identifiable risk factors. Clinical and laboratory monitoring should be considered and APRETUDE should be discontinued if hepatotoxicity is suspected and individuals managed as clinically indicated. For information regarding the long-acting properties of APRETUDE, see previous section. **Depressive Disorders:** Depressive disorders (including depression, depressed mood, major depression, persistent depressive disorder, suicide ideation or attempt) have been reported with APRETUDE. Promptly evaluate individuals with depressive symptoms to assess whether the symptoms are related to APRETUDE and to determine whether the risks of continued therapy outweigh the benefits. **Risk of Reduced Drug Concentration of APRETUDE Due to Drug Interactions:** The concomitant use of APRETUDE and other drugs may result in reduced drug concentration of APRETUDE. See DRUG INTERACTIONS section below for steps to prevent or manage these possible and known significant drug interactions, including dosing recommendations. Consider the potential for drug interactions prior to and during use of, and after discontinuation of APRETUDE; review concomitant medications during use of APRETUDE.

ADVERSE REACTIONS

Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect rates observed in practice. Clinical Trials Experience in Adults: The safety assessment of APRETUDE is based on the analysis of data from 2 international, multicenter, double-blind trials, HPTN 083 and HPTN 084. Adverse reactions were reported while on blinded study product following exposure to APRETUDE extended-release injectable suspension and oral cabotegravir tablets as oral lead-in. The median time on blinded study product in HPTN 083 was 65 weeks and 2 days (range: 1 day to 156 weeks and 1 day), with a total exposure on cabotegravir of 3,231 person-years. The median time on blinded study product in HPTN 084 was 64 weeks and 1 day (range: 1 day to 153 weeks and 1 day), with a total exposure on cabotegravir of 2,009 person-years. The most common adverse reactions regardless of severity reported in at least 1% of participants in HPTN 083 or HPTN 084 are presented in Table 4. In HPTN 083, 6% of participants in the group receiving APRETUDE intramuscular injection every 2 months and 4% of participants receiving oral TRUVADA [emtricitabine (FTC) and tenofovir disoproxil fumarate (TDF)] once daily discontinued due to adverse events (all causality). Non-injection-site–associated adverse events leading to discontinuation and occurring in ≥1% of participants were increased alanine aminotransferase with APRETUDE and TRUVADA. In HPTN 084, 1% of participants receiving APRETUDE and 1% of participants receiving TRUVADA discontinued due to adverse events. The most commonly reported adverse event (all causality) leading to discontinuation was increased alanine aminotransferase (<1%) with APRETUDE and TRUVADA. The side-by-side tabulation is to simplify presentation; direct comparison across trials should not be made due to differing trials.

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Table 4. Adverse Drug Reactions[a] (All Grades) Reported in at Least 1% of Participants Receiving APRETUDE in Either HPTN 083 or HPTN 084

Adverse Reactions	HPTN 083		HPTN 084	
	APRETUDE Every 2 Months (n = 2,281)	TRUVADA Once Daily (n = 2,285)	APRETUDE Every 2 Months (n = 1,614)	TRUVADA Once Daily (n = 1,610)
Injection site reactions[b]	82%	35%	38%	11%
Diarrhea	4%	5%	4%	4%
Headache	4%	3%	12%	13%
Pyrexia[c]	4%	<1%	<1%	<1%
Fatigue[d]	4%	2%	3%	3%
Sleep disorders[e]	3%	3%	1%	1%
Nausea	3%	5%	4%	8%
Dizziness	2%	3%	4%	6%
Flatulence	1%	1%	<1%	<1%
Abdominal pain[f]	1%	1%	2%	2%
Vomiting	<1%	1%	2%	5%
Myalgia	<1%	<1%	2%	1%
Rash[g]	<1%	<1%	2%	1%
Decreased appetite	<1%	<1%	2%	4%
Somnolence	<1%	<1%	2%	2%
Back pain	<1%	<1%	1%	<1%
Upper respiratory tract infection	0	<1%	4%	4%

[a]Adverse reactions defined as "treatment-related" as assessed by the investigator, with exception of injection site reactions, where all injection site reactions were reported regardless of causality.

[b]Participants who received injection: HPTN 083, APRETUDE (n = 2,117) and TRUVADA (n = 2,081); HPTN 084, APRETUDE (n = 1,519) and TRUVADA (n = 1,516).

[c]Pyrexia includes pyrexia, feeling hot, chills, influenza-like illness.

[d]Fatigue includes fatigue, malaise.

[e]Sleep disorders includes insomnia, abnormal dreams.

[f]Abdominal pain includes abdominal pain, upper abdominal pain.

[g]Rash includes rash, erythema, pruritus, macular, papular, maculopapular.

Injection-Associated Adverse Reactions: *Local Injection Site Reactions (ISRs) with APRETUDE:* The most frequent adverse reactions associated with the intramuscular administration of APRETUDE in HPTN 083 were ISRs. After 20,286 injections, 8,900 ISRs were reported. Of the 2,117 participants who received at least one injection of APRETUDE, 1,740 (82%) participants experienced at least one ISR, of which a total of 3% of participants discontinued APRETUDE because of ISRs. Among the participants who received APRETUDE and experienced at least one ISR, the maximum severity of reactions was mild (Grade 1) in 41% of participants, moderate (Grade 2) in 56% of participants, and severe (Grade 3) in 3% of participants. The median duration of overall ISR events was 4 days. The proportion of participants reporting ISRs at each visit and the severity of the ISRs decreased over time. The most commonly reported ISRs (all causality and grades) in at least 1% of participants who received APRETUDE and experienced at least one ISR from HPTN 083 are presented in Table 5. The most frequent adverse reactions associated with the intramuscular administration of APRETUDE in HPTN 084 were ISRs. After 13,068 injections, 1,171 ISRs were reported. Of the 1,519 participants who received at least one injection of APRETUDE, 578 (38%) participants experienced at least one ISR. No participants discontinued APRETUDE because of ISRs. Among the participants who received APRETUDE and experienced at least one ISR, the maximum severity of reactions was mild (Grade 1) in 66% of participants, moderate (Grade 2) in 34% of participants, and severe (Grade 3) in less than 1% of participants. The median duration of overall ISR events was 8 days. The proportion of participants reporting ISRs at each visit and the severity of the ISRs generally decreased over time. The most commonly reported ISRs (all causality and grades) in at least 1% of participants who received APRETUDE and experienced at least one ISR from HPTN 084 are presented in Table 5.

Table 5. Injection Site Reactions (All Grades) Reported in at Least 1% of Participants who Experienced at Least One Injection Site Reaction (All Causality) with APRETUDE in Either HPTN 083 or HPTN 084

Injection Site Reactions	HPTN 083		HPTN 084	
	APRETUDE (n = 1,740)	TRUVADA[a] (n = 724)	APRETUDE (n = 578)	TRUVADA[a] (n = 166)
Pain/ tenderness	98%	95%	90%	87%
Nodules	15%	2%	14%	2%
Induration	15%	<1%	12%	2%
Swelling	12%	1%	18%	3%
Bruising	4%	4%	1%	0
Erythema	4%	2%	5%	2%
Pruritus	3%	3%	6%	11%
Warmth	3%	1%	<1%	0
Anesthesia	1%	2%	1%	2%
Abscess	<1%	0	2%	3%
Discoloration	<1%	0	1%	0

[a]Placebo injectable suspension: intralipid 20% fat emulsion.

Other Injection-Associated Adverse Reactions: In the HPTN 083 clinical trial, an increased incidence of pyrexia (including pyrexia, feeling hot, chills, influenza-like illness) (4%) was reported by participants receiving APRETUDE compared with participants receiving TRUVADA (<1%). There were no differences reported in the incidence of pyrexia between groups in HPTN 084. Vasovagal or pre-syncopal reactions considered treatment related were reported in <1% of participants after injection with APRETUDE in HPTN 083. None were reported as treatment related by the investigators in HPTN 084.

Less Common Adverse Reactions: The following select adverse reactions (regardless of severity) occurred in <1% of participants receiving APRETUDE in HPTN 083 or HPTN 084: *Hepatobiliary Disorders:* Hepatotoxicity. *Investigations:* Weight increase *(see below). Psychiatric Disorders:* Depression.

Weight Increase: At the Week 41 and Week 97 timepoints in HPTN 083, participants who received APRETUDE gained a median of 1.2 kg (Interquartile Range [IQR]; -1.0, 3.5; n = 1,623) and 2.1 kg (IQR; -0.9, 5.9; n = 601) in weight from baseline. Those who received TRUVADA gained a median of 0 kg (IQR; -2.1, 2.4; n = 1,611) and 1 kg (IQR; -1.9, 4.0; n = 598) in weight from baseline, respectively. At the Week 41 and 97 timepoints in HPTN 084, participants who received APRETUDE gained a median of 2 kg (IQR; 0.0, 5.0; n = 1,151) and 4 kg (IQR; 0.0, 8.0; n = 216) in weight from baseline, respectively. Those who received TRUVADA gained a median of 1 kg (IQR; -1.0, 4.0; n = 1,131) and 3 kg (IQR; -1.0, 6.0; n = 218) in weight from baseline, respectively.

Laboratory Abnormalities: Grade 3 or 4 post-baseline maximum toxicity laboratory abnormalities for HPTN 083 or HPTN 084 are summarized in Table 6.

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Table 6. Laboratory Abnormalities (Grades 3 to 4) in ≥1% of Participants in Either HPTN 083 or HPTN 084

Laboratory Parameter	HPTN 083		HPTN 084	
	APRETUDE Every 2 Months (n = 2,281)	TRUVADA Once Daily (n = 2,285)	APRETUDE Every 2 Months (n = 1,614)	TRUVADA Once Daily (n = 1,610)
ALT (≥5.0 x ULN)	2%	2%	<1%	1%
AST (≥5.0 x ULN)	3%	3%	<1%	<1%
Creatine phosphokinase (≥10.0 x ULN)	15%	14%	2%	2%
Lipase (≥3.0 x ULN)	3%	3%	<1%	<1%
Creatinine (>1.8 x ULN or increase to ≥1.5 x baseline)	3%	3%	5%	4%

ALT = Alanine transaminase, ULN = Upper limit of normal, AST = Aspartate aminotransferase.

Serum Lipids: Changes from baseline to Month 15 in total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides, and total cholesterol to HDL ratio in HPTN 083 and HPTN 084 are presented in Table 7.

Table 7. Fasting Lipid Values, Median Change from Baseline[a] at Week 57, Reported in HPTN 083 and HPTN 084

	HPTN 083		HPTN 084	
	APRETUDE	TRUVADA	APRETUDE	TRUVADA
Total cholesterol (mg/dL)	+1.0	-10.0	+0.2	-3.9
LDL cholesterol (mg/dL)	+1.0	-6.0	-1.1	-5.0
HDL cholesterol (mg/dL)	-0.2	-3.0	-0.8	-2.6
Triglycerides (mg/dL)	+2.7	0.0	+3.1	+0.7
Total cholesterol: HDL cholesterol ratio	+0.1	+0.0	+0.1	+0.1

[a]Nearly 60% of participants with baseline data available had Week 57 data available in both arms of both trials. Within each trial, baseline values were comparable among participants receiving APRETUDE and TRUVADA.

Clinical Trials Experience in Adolescents: In adolescents receiving APRETUDE for HIV-1 PrEP, the safety data were comparable to the safety data reported in adults receiving APRETUDE for HIV-1 PrEP.

Postmarketing Experience

The following adverse reactions have been identified during postmarketing use of cabotegravir-containing regimens. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Immune System Disorders

Hypersensitivity reactions (including angioedema and urticaria).

DRUG INTERACTIONS

Use of Other Antiretroviral Drugs after Discontinuation of APRETUDE: Residual concentrations of cabotegravir may remain in the systemic circulation of individuals for prolonged periods (up to 12 months or longer). These residual concentrations are not expected to affect the exposures of antiretroviral drugs that are initiated after discontinuation of APRETUDE. **Potential for Other Drugs to Affect APRETUDE:** Cabotegravir is primarily metabolized by UGT1A1 with some contribution from UGT1A9. Drugs that are strong inducers of UGT1A1 or 1A9 are expected to decrease cabotegravir plasma concentrations; therefore, coadministration of APRETUDE with these drugs is contraindicated. **Established and Other Potentially Significant Drug Interactions:** Information regarding potential drug interactions with cabotegravir is provided below. These recommendations are based on either drug interaction trials following oral administration of cabotegravir or predicted interactions due to the expected magnitude of the interaction. The information below includes potentially significant interactions but is not all inclusive.

- **Anticonvulsants:** carbamazepine, oxcarbazepine, phenobarbital, phenytoin – coadministration is contraindicated with APRETUDE due to potential for significant decreases in plasma concentration of APRETUDE
- **Antimycobacterials:** rifampin, rifapentine – coadministration is contraindicated with APRETUDE due to potential for significant decreases in plasma concentration of APRETUDE
- **Antimycobacterial:** rifabutin – when rifabutin is started before or concomitantly with the first initiation injection of APRETUDE, the recommended dosing of APRETUDE is one 600-mg (3-mL) injection, followed 2 weeks later by a second 600-mg (3-mL) initiation injection and monthly thereafter while on rifabutin. When rifabutin is started at the time of the second initiation injection or later, the recommended dosing schedule of APRETUDE is 600 mg (3 mL) monthly while on rifabutin. After stopping rifabutin, the recommended dosing schedule of APRETUDE is 600 mg (3 mL) every 2 months

Drugs without Clinically Significant Interactions with Cabotegravir: Based on drug interaction study results, the following drugs can be coadministered with cabotegravir (non-antiretrovirals) or given after discontinuation of cabotegravir (antiretrovirals and non-antiretrovirals) without a dose adjustment: etravirine, midazolam, oral contraceptives containing levonorgestrel and ethinyl estradiol, and rilpivirine.

Consult the full Prescribing Information for potential drug interactions; this list is not all inclusive.

USE IN SPECIFIC POPULATIONS

Pregnancy: Pregnancy Exposure Registry: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to APRETUDE during pregnancy. Healthcare providers are encouraged to register individuals by calling the Antiretroviral Pregnancy Registry (APR) at 1-800-258-4263. Risk Summary: There are insufficient human data on the use of APRETUDE during pregnancy to adequately assess a drug-associated risk of birth defects and miscarriage. While there are insufficient human data to assess the risk of neural tube defects (NTDs) with exposure to APRETUDE during pregnancy, NTDs were associated with dolutegravir, another integrase inhibitor. Discuss the benefit-risk of using APRETUDE with individuals of childbearing potential or during pregnancy. Cabotegravir use in pregnant women has not been evaluated. APRETUDE should be used during pregnancy only if the expected benefit justifies the potential risk to the fetus. The APR has been established to monitor for birth defects following prenatal exposure to antiretrovirals. The rate of miscarriage is not reported in the APR. The background rate for major birth defects in a U.S. reference population of the Metropolitan Atlanta Congenital Defects Program (MACDP) is 2.7%. The estimated background rate of miscarriage in clinically recognized pregnancies in the U.S. general population is 15% to 20%. The APR uses the MACDP as the U.S. reference population for birth defects in the general population. The MACDP evaluates women and infants from a limited geographic area and does not include outcomes for births that occurred at <20 weeks' gestation. In animal reproduction studies with oral cabotegravir, a delay in the onset of parturition and increased stillbirths and neonatal deaths were observed in a rat pre- and postnatal development study at >28 times the exposure at the recommended human dose (RHD). No evidence of adverse developmental outcomes was observed with oral cabotegravir in

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rats or rabbits (>28 times or similar to the exposure at the RHD, respectively) given during organogenesis *(see Data)*. Clinical Considerations: Cabotegravir is detected in systemic circulation for up to 12 months or longer after discontinuing injections of APRETUDE; therefore, consideration should be given to the potential for fetal exposure during pregnancy. Data: *Human Data:* Data from a birth outcome surveillance study in Botswana showed that dolutegravir, another integrase inhibitor, was associated with increased risk of NTDs when administered at the time of conception and in early pregnancy. Data from clinical trials are insufficient to address this risk with cabotegravir. *Animal Data:* Cabotegravir was administered orally to pregnant rats at 0, 0.5, 5, or 1,000 mg/kg/day from 15 days before cohabitation, during cohabitation, and from Gestation Days 0 to 17. There were no effects on fetal viability when fetuses were delivered by caesarean, although a minor decrease in fetal body weight was observed at 1,000 mg/kg/day (>28 times the exposure in humans at the RHD). No drug-related fetal toxicities were observed at 5 mg/kg/day (approximately 13 times the exposure in humans at the RHD), and no drug-related fetal malformations were observed at any dose. Cabotegravir was administered orally to pregnant rabbits at 0, 30, 500, or 2,000 mg/kg/day from Gestation Days 7 to 19. No drug-related fetal toxicities were observed at 2,000 mg/kg/day (approximately 0.7 times the exposure in humans at the RHD). In a rat pre- and postnatal development study, cabotegravir was administered orally to pregnant rats at 0, 0.5, 5, or 1,000 mg/kg/day from Gestation Day 6 to Lactation Day 21. A delay in the onset of parturition and increases in the number of stillbirths and neonatal deaths by Lactation Day 4 were observed at 1,000 mg/kg/day (>28 times the exposure in humans at the RHD); there were no alterations to growth and development of surviving offspring. In a cross-fostering study, similar incidences of stillbirths and early postnatal deaths were observed when rat pups born to cabotegravir-treated mothers were nursed from birth by control mothers. There was no effect on neonatal survival of control pups nursed from birth by cabotegravir-treated mothers. A lower dose of 5 mg/kg/day (13 times the exposure at the RHD) was not associated with delayed parturition or neonatal mortality in rats. Studies in pregnant rats showed that cabotegravir crosses the placenta and can be detected in fetal tissue. **Lactation:** Risk Summary: It is not known if cabotegravir is present in human breast milk, affects human milk production, or has effects on the breastfed infant. When administered to lactating rats, cabotegravir was present in milk *(see Data)*. If cabotegravir is present in human milk, residual exposures may remain for 12 months or longer after the last injections have been administered. Because of detectable cabotegravir concentrations in systemic circulation for up to 12 months or longer after discontinuing injections of APRETUDE, it is recommended that women breastfeed only if the expected benefit justifies the potential risk to the infant. Data: *Animal Data:* Animal lactation studies with cabotegravir have not been conducted. However, cabotegravir was detected in the plasma of nursing pups on Lactation Day 10 in the rat pre- and postnatal development study. **Pediatric Use:** The safety and effectiveness of APRETUDE for HIV-1 PrEP in at-risk adolescents weighing at least 35 kg is supported by data from 2 adequate and well-controlled trials of APRETUDE for HIV-1 PrEP in adults with additional safety and pharmacokinetic data from studies in HIV-1–infected adults who were administered CABENUVA, and in HIV-1–infected pediatric subjects who were administered separate components of CABENUVA in addition to their current antiretroviral therapy. APRETUDE for HIV-1 PrEP is being evaluated in 2 open-label multicenter clinical trials in adolescent individuals. Fifty-nine adolescents have been enrolled. Of these, 54 adolescent participants received one or more injections. In adolescents receiving APRETUDE for HIV-1 PrEP, the safety data were comparable to the safety data reported in adults receiving APRETUDE for HIV-1 PrEP. While using APRETUDE, HIV-1 testing should be conducted prior to initiating APRETUDE (with or without an oral lead-in with oral cabotegravir) and prior to each injection of APRETUDE. Adolescents may benefit from more frequent visits and counseling to support adherence to the dosing and testing schedule. The safety, efficacy, and pharmacokinetics of APRETUDE in pediatric participants younger than 12 years of age or weighing <35 kg have not been established. **Geriatric Use:** No dose adjustment is required in elderly individuals. There are limited data available on the use of APRETUDE in individuals aged 65 years and older. In general, caution should be exercised in administration of APRETUDE in elderly individuals, reflecting greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy. **Renal Impairment:** Based on studies with oral cabotegravir, no dosage adjustment of APRETUDE is necessary for individuals with mild (creatinine clearance ≥60 to <90 mL/min) or moderate renal impairment (creatinine clearance ≥30 to <60 mL/min). In individuals with severe renal impairment (creatinine clearance 15 to <30 mL/min) or end-stage renal disease (creatinine clearance <15 mL/min), increased monitoring for adverse effects is recommended. In individuals with end-stage renal disease not on dialysis, effects on the pharmacokinetics of cabotegravir are unknown. As cabotegravir is >99% protein bound, dialysis is not expected to alter exposures of cabotegravir. **Hepatic Impairment:** Based on studies with oral cabotegravir, no dosage adjustment of APRETUDE is necessary for individuals with mild or moderate hepatic impairment (Child-Pugh A or B). The effect of severe hepatic impairment (Child-Pugh C) on the pharmacokinetics of cabotegravir is unknown.

OVERDOSAGE

There is no known specific treatment for overdose with APRETUDE. If overdose occurs, monitor the individual and apply standard supportive treatment as required as well as observation of the clinical status of the individual. As APRETUDE is highly bound to plasma proteins, it is unlikely that it will be significantly removed by dialysis. Consider the prolonged exposure to APRETUDE following an injection when assessing treatment needs and recovery.

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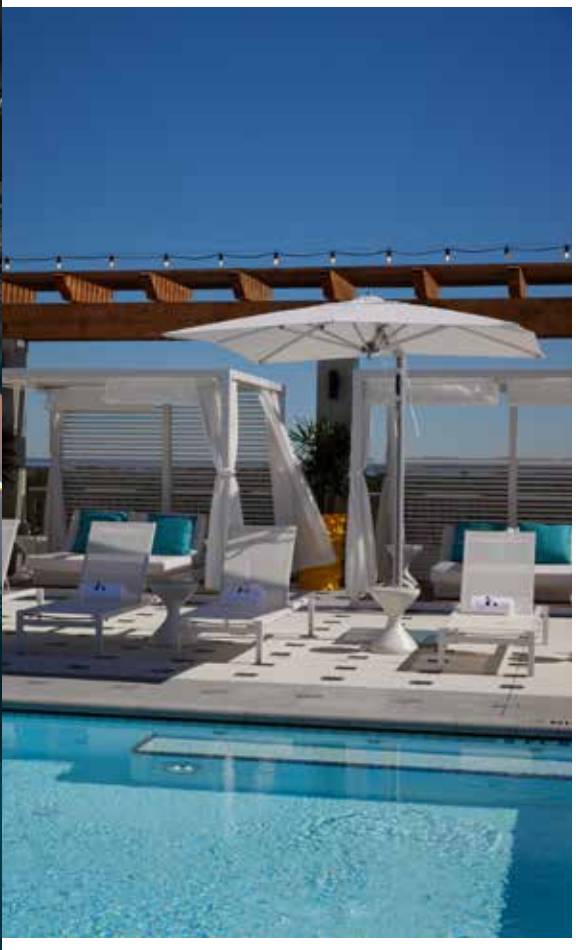
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- PAD symptoms are often mistaken for arthritis or old age.

The simpleABI Cuff-Link System is Easy to Learn and Use.
- With a push-button remote, automatic calculations, and waveforms, it's incredibly user-friendly.
- Reports are straightforward to save and share since the system is PC-based.

Outstanding Value and Reimbursements
- The system pays for itself in less than a year with just one test per week.
- Medicare reimbursements vary by exam and location, averaging from $91 to $174.

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BONE HEALTH

WHY BINDEX® IS A GAME-CHANGER IN OSTEOPOROSIS DIAGNOSTICS.

From Bindex Medical

Comparable to DXA
Extensive clinical research has proven Bindex to be 90% accurate in detecting osteoporosis. It can replace nearly 70% of DXA scans for patients with suspected osteoporosis.

Fast and effective
Using safe pulse-echo ultrasound to measure cortical bone thickness, Bindex analyzes bone density in just seconds.

Easy to use anywhere
Lightweight and pocket-sized, Bindex allows patients to receive on-the-spot bone density scans in doctors' offices, hospitals and clinics and at home.

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3410

BRAIN FUNCTION ASSESSMENT

3411



EARLIER DETECTION OF MEMORY LOSS, DEMENTIA AND OTHER COGNITIVE DISORDERS

From Morningside Medical

Standard cognitive screening tools like MMSE/ MOCA are exactly that; screening tools. The technology is there to test the patients that fail these screening tools right in your office. Get clinically relevant information about your patients' brain performance, while generating additional reimbursement for the practice, leading to earlier diagnosis and more accurate referrals.

Aids in clear diagnosis • Strong Reimbursement • Improves Patient Outcomes • Easy for any staff to perform • Cognitive Testing / Mental Health • Sudomotor Function / Neuropathy • Vestibular Testing / Fall Prevention • Autonomic Function / Cardiovascular Risk

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BRAIN FUNCTION ASSESSMENT

MEMORY LOSS BIOMARKERS TO AID IN DIAGNOSIS IN PRIMARY CARE PRACTICES

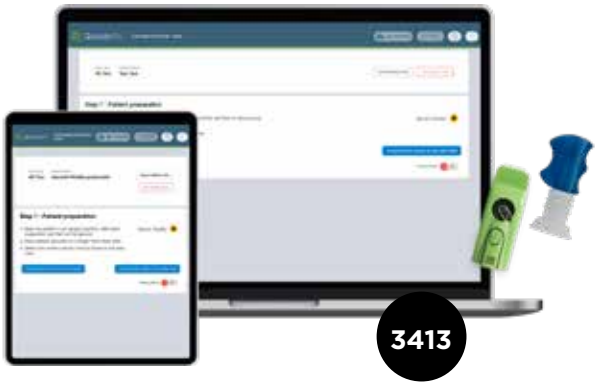
From Evoke Neuroscience

The eVox® System is an FDA 510(k) cleared medical device to aid primary and specialty care physicians in diagnosis of memory loss and other cognitive disorders. eVox® measures memory loss biomarkers that may aid in detecting memory loss sooner, identifying the root cause of memory loss, and performing a differential diagnosis. eVox® procedures are performed in-office and are reimbursable by Medicare and commercial payers.

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CARDIOLOGY



QUANTAFLO® HD

From Semler Scientific

The QuantaFlo® HD application assists in the early detection of Heart Dysfunction (HD). As published in the Journal of Preventive Medicine, QuantaFlo HD showed a statistically significant correlation with cardiac echocardiography, which is a gold standard for diagnosing heart failure.1 The test is highly sensitive, able to detect even asymptomatic HD, and can be performed in the outpatient clinic or the home setting in approximately 5 mins. Results are available immediately and graded as either positive or negative for HD allowing for improved patient selection for echocardiography.

1. Howell, S. C., & Master, R. C. (2023). Clinical Evaluation of Volume Plethysmography as an Aid for Diagnosis of Heart Failure in the Primary Care Setting. Journal of Preventive Medicine, 8(2). https://doi.org/https://preventive-medicine.imedpub.com/clinical-evaluation-of-volume-plethysmography-as-an-aid-for-diagnosis-of-heart-failure-in-the-primary-care-setting.pdf

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CHEMISTRY ANALYZERS

DC-LINEATE CALIBRATION/ LINEARITY MATERIAL

From SEKISUI Diagnostics

The DC-Lineate is a unique, trilevel calibration/linearity material that is used in conjunction with assays for the quantitative determination of UIBC levels in clinical samples. The material is conveniently packaged in a 2 x 5 mL configuration for each of the three levels and is traceable back to the National Institute of Standards and Technology (NIST). It can be used on a broad range of clinical chemistry analyzers and has a shelf life up to 14-days after reconstitution.

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DIAZYME DZ-LITE™ C270 BENCHTOP GENERAL/SPECIAL CHEMISTRIES + DRUG SCREENS

From Carolina Liquid Chemistries

A fully-automated, open system, benchtop clinical chemistry analyzer with throughput up to 270 tests/hour, 36 reagent positions, and 30 sample positions. It features a menu of over 60 CLIA moderate complexity assays, including cancer markers, cardiovascular markers, coagulation markers, diabetic markers, inflammatory markers, liver markers, renal/pancreatic markers, sepsis markers, vitamin markers, photometric electrolytes, and drugs of abuse. To learn more, visit https://www.carolinachemistries.com/products/dz-lite-c270-benchtop-chemistry-analyzer/.

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Enter Number **3415** in the Search Area

FIRST EVER FDA-CLEARED AND CATEGORIZED, POINT-OF-CARE FENTANYL TEST (<6 MINUTES)

From Carolina Liquid Chemistries

Carolina Liquid Chemistries Corp. introduces the Fentanyl Urine Detection Test on CLC's next-generation RYAN™ immunofluorescent analyzer. This FDA cleared and CLIA categorized, moderately complex, compact, point-of-care system detects fentanyl qualitatively in human urine at a cutoff concentration of 1.0 ng/mL. The test can be run in < 6 minutes, produces a chartable result, and is interfaceable. For detailed information, visit carolinachemistries.com/products/fentanyl-urine-detect-on-clc-ryan-analyzer/.

View Brochures, Videos & More at POR.io
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ENVOY500+ DELIVERING PROVEN RESULTS IN CLINICAL CHEMISTRY

From EliTech

The fully automated Envoy500+ is designed to deliver the performance of a large floor model analyzer but provides the cost efficiency of a benchtop analyzer (TPH approx. 490). It enables accurate treatment decisions sooner. Envoy500+ delivers savings the laboratory requires with the following features positive sample and reagent identification, clot detection, liquid level sensing, dry ISE module, reusable glass cuvettes, and many more.

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TOXICOLOGY SCREENING SIMPLIFIED ABBOTT'S IMMTOX 270 BENCHTOP ANALYZER NOW WITH 14 ASSAYS CLIA CATEGORIZED AS MODERATE COMPLEXITY

From Abbott

The ImmTox270 benchtop analyzer offers comprehensive toxicology screening solutions for physician offices, treatment centers and independent laboratories.

Broad test menu with over 20 assays to choose from including 14 that are now available as moderately complex.

With complete laboratory solutions from consultation to licensure, and compliance the Abbott Clinical Laboratory Solutions team has you covered.

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3419

EASY, INTEGRATED WITH-PATIENT TESTING I-STAT SYSTEM

From Abbott Point of Care

The handheld i-STAT System offers a broad menu of diagnostic tests at the patient's side in just minutes. With just a few drops of blood, the i-STAT System delivers real time, lab-accurate results for a wide range of tests, including chemistries, blood gas, coagulation, cardiac markers, and more. Minimize delays and wasted time with on-side tests. Easy, intuitive operation.

For intended use and complete product information, visit pointofcare.abbott.

For in vitro diagnostic use only. This material is intended for a U.S. audience only. i-STAT is a trademark of Abbott. Physician Office Resource i-STAT Product Description — US 3064.REV1 08/20

View Brochures, Videos & More at POR.io
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PENTRA C400 CHEMISTRY ANALYZER

From HORIBA Medical

One benchtop, not a whole lab! No water system, drain or special electrical connected required to operate the Pentra C400 chemistry analyzer. Now you can have the power of a floor model analyzer on the benchtop! The Pentra C400 chemistry system processes up to 420 tests/hr including ISEs and offers routine metabolic assays, TDMs, DAUs and Adulterants, HbA1c and Vitamin D tests. With 40 open channels, you can add much more for a complete menu to meet your practice needs.

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3421

FULL COMPLEMENT OF CLIA-WAIVED BLOOD CHEMISTRY TESTS PICCOLO XPRESS® CHEMISTRY ANALYZER

From Abbott Point of Care

The Piccolo Xpress Chemistry Analyzer provides physician offices with lab-accurate results for a broad range of CLIA-waived general chemistry tests, including metabolic panels, lipids, live, and kidney function, and more with just 100 microliters of blood. Easy to use, the PIccolo Xpress provides results during a patient's visit, accelerating treatment decisions, increasing efficiency, and supporting patient satisfaction. Automated quality control on every test helps ensure accuracy.

View Brochures, Videos & More at POR.io
Enter Number **3421** in the Search Area

RX DAYTONA+

From Randox Laboratories

The RX daytona+ is a fully automated, benchtop, clinical chemistry analyzer capable of performing high quality testing, with a combined throughput of 450 tests per hour, for accurate results you can trust. The most versatile analyzer in its class, the RX daytona+ combines robust hardware and intuitive software with the world leading RX series test menu for unrivaled performance, with direct HbA1c testing capabilities.

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Enter Number **3422** in the Search Area



3422



3423

RX IMOLA

From HORIBA Medical

The RX imola is a cost-effective system that delivers consistent high-quality results. Capable of handling the workload of a medium to high throughout laboratory and a combined throughput of 560 tests per hour, the RX imola provides rapid, comprehensive testing on a small footprint analyzer when it matters most, with direct HbA1c testing capabilities.

View Brochures, Videos & More at POR.io
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LumiraDx™

Not all Antigen Tests are Created Equal



The LumiraDx SARS-CoV-2 Ag test utilizes next-generation microfluidic technology, bringing lab-comparable performance to the point of care.

- 97.6% positive agreement to RT-PCR in patients up to 12 days following symptom onset • Microfluidic immunofluorescence assay
- Easy to use • Results in minutes • Small, low-waste consumable
- CLIA Waived*



3424

Scan to learn more.
LumiraDx.com

*The LumiraDx SARS-CoV-2 Ag test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This product has not been FDA cleared or approved but has been authorized by FDA under an EUA for use by authorized laboratories. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the declaration is terminated, or authorization is revoked sooner. S-COM-ART-02381 R3 2022/11

CHEMISTRY ANALYZERS



TOXICOLOGY URINE DRUG SCREENING REAGENTS

From Abbott

Prescription drug misuse and illicit drug abuse is a growing public health challenge in this country. Building a test profile that covers highly misused drugs has never been so vital. With over 20 relevant assays to choose from Abbott's suite of Immunalysis reagents allows you to easily screen for relevant substances. Our complete line of assays, calibrators, and controls enables you to implement an efficient drug screening program in office.

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CLIA WAIVED

ACUCY INFLUENZA A&B TEST

From Sekisui Diagnostics

The Acucy™ Influenza A&B Test is for the rapid, qualitative detection of influenza A and B viral nucleoprotein antigens from both nasal and nasopharyngeal swabs. Utilizing the Acucy™ Reader in either the point-of-care or laboratory setting, workflow flexibility is achieved with both Read Now and Walk Away features. The combination provides clinicians with standardized and definitive result interpretation.

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LAB-ACCURATE RESULTS FOR ACR AND HBA1C

From Abbott

With its compact size and panel of tests, the Afinion 2 system is ideal for point-of-care testing in physician offices, clinics, community health centers and hospital out-patient clinics. From just a small urine or fingerstick whole blood sample, lab-accurate results for ACR and HbA1c are made available during the consultation.

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Enter Number **3427** in the Search Area

BIOFIRE SPOTFIRE

From bioMerieux

bioMérieux knows that an evolving world deserves evolved diagnostics. Our latest innovation, the BIOFIRE® SPOTFIRE® Respiratory Solution, is the first FDA-cleared and CLIA-waived COVID-19 testing solution. The BIOFIRE® SPOTFIRE® System is an easy-to-use system that runs the BIOFIRE® SPOTFIRE® Respiratory (R) Panel. Benefits of the SPOTFIRE Respiratory Solution include: 15 respiratory targets on 1 PCR test with results in about 15 minutes; minimal benchtop space with vertical scalability up to four modules; easy to use with an intuitive user interface.

View Brochures, Videos & More at POR.io
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ACCURATE, ACTIONABLE RESULTS FROM THE LEADER IN POINT-OF-CARE LIPID TESTING

From Abbott

The CLIA-waived Alere Cholestech LDX™ Analyzer is engineered for confidence, providing accurate, actionable, and readily accessible results that have set the standard in point-of-care lipid profile, cholesterol, and glucose testing. Results are easy to obtain. Fingerstick sampling and a small sample size (40µL) makes results less painful and time consuming.

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OSOM® BVBLUE®

From Sekisui Diagnostics

The OSOM® BVBLUE® detects elevated vaginal fluid sialidase activity, an enzyme produced by bacterial pathogens associated with bacterial vaginosis including Gardnerella, Bacteroides, Prevotella and Mobiluncus. OSOM® BVBLUE® is more sensitive than Amsel criteria providing physicians with a more accurate diagnosis to treat and minimize serious health consequences such as early spontaneous preterm births and miscarriage.

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OSOM® TRICHOMONAS RAPID TEST

From Sekisui Diagnostics

The OSOM® Trichomonas Rapid Test is intended for the qualitative detection of Trichomonas vaginalis antigens from vaginal swabs or from the saline solution. The OSOM® Trichomonas Rapid Test is a CLIA-waived rapid test available today. OSOM® Trichomonas is more sensitive than wet mount due to the assay being able to detect viable and non-viable organisms which offers significant benefits to the patient and clinician alike.

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OSOM ULTRA PLUS FLU A&B TEST

From Sekisui Diagnostics

Stronger Clinical Performance Takes Lateral Flow Testing To The Next Level. Providing superior rapid results at the point-of-care. Fast, easy, cost effective so you can test and treat in one visit.

- High Performance- Equivalent or exceeding the performance of reader devices, without the need for an instrument
- Results in 10 minutes
- OSOM® Custom Care- Exceptional Support/Training by licensed medical technologists and experienced healthcare professionals
- Made in the USA

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OSOM® ULTRA STREP A TEST

From Sekisui Diagnostics

The OSOM® Ultra Strep A test is a color immunochromatographic assay intended for the qualitative detection of Group A Streptococcus antigen directly from throat swab specimens. Shown to be not statistically different than single swab culture. Sensitivity 95.7% and 100% Specificity. Includes two additional test sticks for External QC. CLIA Waived..

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CLIA WAIVED

ULTRA HCG COMBO TEST

From Sekisui Diagnostics

The OSOM® Ultra hCG Combo test is a simple immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in serum or urine for the early confirmation of pregnancy. Internal studies have confirmed that the OSOM® Ultra hCG Combo test does not have a false negative result from hCG variants providing physicians with a higher level of confidence.

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FIRST EVER CLIA WAIVED HEMATOLOGY ANALYZER

From Sysmex

Faster test results, clinical decisions and greater practice efficiency are coming to physicians' offices with the first CLIA-waived CBC analyzer. Hematology diagnostics leader Sysmex is bringing more lab testing to the point of care. One of the most common blood tests can be conducted reliably and accurately on-site, in as few as three minutes. The device's ease of use and innovative technology means in-house staff can operate it in just a few easy steps, without lengthy certification and training. The new Sysmex XW-100 will improve health care efficiency and patient care.

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COVID-19 TESTING

BD VERITOR™ PLUS SYSTEM

From BD Veritor™

The BD Veritor™ Plus System is a portable, easy-to-use, testing solution for SARS-COV-2*, Flu A+ B and other respiratory tract infections that delivers results in 15 minutes or less. It features two analysis modes that adapt to your workflow, online education tools, and optional reporting capabilities including the BD Synapsys™ Informatics Solution—making it the point-of-care diagnostic tool you won't want to be without.

*EUA authorized by FDA

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3437

BIOFIRE SPOTFIRE

From bioMerieux

bioMérieux knows that an evolving world deserves evolved diagnostics. Our latest innovation, the BIOFIRE® SPOTFIRE® Respiratory Solution, is the first FDA-cleared and CLIA-waived COVID-19 testing solution. The BIOFIRE® SPOTFIRE® System is an easy-to-use system that runs the BIOFIRE® SPOTFIRE® Respiratory (R) Panel. Benefits of the SPOTFIRE Respiratory Solution include: 15 respiratory targets on 1 PCR test with results in about 15 minutes; minimal benchtop space with vertical scalability up to four modules; easy to use with an intuitive user interface.

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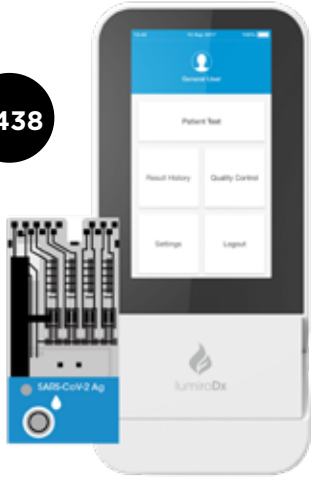
WHY COMPROMISE? FAST AND RELIABLE RESULTS ARE NOW DELIVERED AT THE POINT OF CARE.

From LumiraDx

Introducing the next generation in point-of-care diagnostics. With a growing menu of tests, LumiraDx uses a simple process that allows for more time with your patients by using microfluidic technology that delivers results in minutes. Learn more about rapid COVID-19 diagnostic solutions for your physician office at LumiraDx.com.

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3438





3439

BE PREPARED FOR RESPIRATORY SEASONS WITH THE OSOM® COVID-19 ANTIGEN RAPID TEST

From Sekisui

The OSOM® COVID-19 Antigen Rapid Test is a lateral flow immunoassay that detects the SARS-CoV-2 nucleocapsid protein with a nasal swab in only 15 minutes at the point-of-care. The test is intended to be used by healthcare professionals or operators on patients suspected of COVID-19 within the first 7 days of symptom onset. The clinical performance compares favorably against polymerase chain reaction methodology, with a positive percent agreement of 95.1% and a negative percent agreement of 97%.

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OSOM® COVID-19 Antigen Rapid Test has not been FDA cleared or approved. It is authorized by FDA under an EUA for prescription use only. It has been authorized only for the detection of SARS-CoV-2 antigen, not for any other viruses or pathogens and is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C S360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

COVID-19 TESTING

SOFIA® 2 FLUORESCENT IMMUNOASSAY ANALYZER AND RAPID DIAGNOSTIC TEST KITS

From Quidel

Sofia® 2 Fluorescent Immunoassay Analyzer and Rapid Diagnostic Test Kits Sofia 2 takes rapid testing to a new level. Proven lateral-flow technology and advanced fluorescent chemistry are all integrated into this small benchtop analyzer which can be used in any point-of-care setting. Sofia 2 kits are easy to use and adaptable to any healthcare setting. Excellent performance, objectivity, quality control, LIS capabilities, and an expanding test menu make Sofia 2 the perfect solution for the physician's office laboratory.

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DIABETES/BLOOD GLUCOSE



LAB-ACCURATE RESULTS FOR ACR AND HBA1C

From Abbott

With its compact size and panel of tests, the Afinion 2 system is ideal for point-of-care testing in physician offices, clinics, community health centers and hospital out-patient clinics. From just a small urine or fingerstick whole blood sample, lab-accurate results for ACR and HbA1c are made available during the consultation.

View Brochures, Videos & More at POR.io
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ACCURATE, ACTIONABLE RESULTS FROM THE LEADER IN POINT-OF-CARE LIPID TESTING

From Abbott

The CLIA-waived Alere Cholestech LDX™ Analyzer is engineered for confidence, providing accurate, actionable, and readily accessible results that have set the standard in point-of-care lipid profile, cholesterol, and glucose testing. Results are easy to obtain. Fingerstick sampling and a small sample size (40µL) makes results less painful and time consuming.

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COMPREHENSIVE IN-OFFICE DIABETES TESTING WITH THE DCA VANTAGE® AND CLINITEK STATUS®+ ANALYZERS

From Siemens Healthineers

Siemens Healthineers DCA Vantage® and CLINITEK Status® family of analyzers provide hemoglobin A1c (HbA1c) and albumin-to-creatinine ratio (ACR) testing at the point of care. Meet quality measures for A1c control and kidney disease check in minutes with CLIA-waived HbA1c testing and ACR[1] ratio. Improve patient experience and overall outcome by providing actionable results in minutes.

1. Moderately complex on the DCA Vantage Analyzer. CLIA-waived on the CLINITEK Status+ Analyzer.

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INSULIN INSIGHTS

From Semler Scientific

Using algorithms that codify the ADA standards of care Insulin Insights' game-changing technology empowers clinicians with actionable data to help inform insulin dosing decisions. This FDA-cleared software as a medical device aims to improve diabetic patient outcomes, lower glycated hemoglobin, and reduce the risk of long-term complications. It is the only comprehensive dosing solution for all patients and insulin regimens.

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NOVA PRIMARY BLOOD GLUCOSE REFERENCE ANALYZER

From Nova Biomedical

The U.S. FDA has cleared Nova Primary as a blood glucose reference analyzer that fills the need for a new reference analyzer to replace the YSI STAT PLUS 2300 (YSI, Inc., Yellow Springs, OH). Manufacturers of blood glucose measuring devices and clinical diabetes researchers have relied on the YSI 2300 as a reference and correlation analyzer. However, YSI, Inc. no longer supports the analyzer, and its discontinuation has left a critical industry void. With today's FDA clearance, Nova Primary from Nova Biomedical is now available in the U.S. and worldwide.

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DIABETES/BLOOD GLUCOSE

QUANTAFLO® PAD

From Semler Scientific



QuantaFlo® PAD is an easy to use, accurate, point of care, non-invasive solution that aids in the early detection of peripheral arterial disease (PAD). This FDA cleared device can be administered by a medical aide in less than 5 minutes. As published in the Journal of Vascular Surgery and the American Journal of Preventive Medicine, QuantaFlo detected undiagnosed PAD in 31.6% of patients +65.1 QuantaFlo is portable and integrates with other technologies and platforms. It is ideal for both home and clinic environments.

1. Smolderen KG, Ameli O, Chaisson CE, Heath K, Mena-Hurtado C. Peripheral Artery Disease Screening in the Community and 1-Year Mortality, Cardiovascular Events, and Adverse Limb Events, AJPM Focus (2022), https://doi.org/10.1016/j.focus.2022.100016

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FLU AND RESPIRATORY



ACUCY INFLUENZA A&B TEST

From Sekisui Diagnostics

The Acucy™ Influenza A&B Test is for the rapid, qualitative detection of influenza A and B viral nucleoprotein antigens from both nasal and nasopharyngeal swabs. Utilizing the Acucy™ Reader in either the point-of-care or laboratory setting, workflow flexibility is achieved with both Read Now and Walk Away features. The combination provides clinicians with standardized and definitive result interpretation.

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BD VERITOR™ PLUS SYSTEM

From BD Veritor™



The BD Veritor™ Plus System is a portable, easy-to-use, testing solution for SARS-COV-2*, Flu A+ B and other respiratory tract infections that delivers results in 15 minutes or less. It features two analysis modes that adapt to your workflow, online education tools, and optional reporting capabilities including the BD Synapsys™ Informatics Solution—making it the point-of-care diagnostic tool you won't want to be without.

*EUA authorized by FDA

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3449

BIOFIRE SPOTFIRE

From bioMerieux

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SOFIA® 2 FLUORESCENT IMMUNOASSAY ANALYZER AND RAPID DIAGNOSTIC TEST KITS

From Quidel

Sofia® 2 Fluorescent Immunoassay Analyzer and Rapid Diagnostic Test Kits Sofia 2 takes rapid testing to a new level. Proven lateral-flow technology and advanced fluorescent chemistry are all integrated into this small benchtop analyzer which can be used in any point-of-care setting. Sofia 2 kits are easy to use and adaptable to any healthcare setting. Excellent performance, objectivity, quality control, LIS capabilities, and an expanding test menu make Sofia 2 the perfect solution for the physician's office laboratory.

View Brochures, Videos & More at POR.io
Enter Number **3450** in the Search Area



3450



3451

OSOM ULTRA PLUS FLU A&B TEST

From Sekisui Diagnostics

Stronger Clinical Performance Takes Lateral Flow Testing To The Next Level. Providing superior rapid results at the point-of-care. Fast, easy, cost effective so you can test and treat in one visit.

- High Performance- Equivalent or exceeding the performance of reader devices, without the need for an instrument
- Results in 10 minutes
- OSOM® Custom Care- Exceptional Support/Training by licensed medical technologists and experienced healthcare professionals
- Made in the USA

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Enter Number **3451** in the Search Area

PENTRA 60 C+ HEMATOLOGY ANALYZER WITH 5-PART DIFFERENTIAL

From HORIBA Medical

Now you can have the same results hospitals and reference labs provide in a small, benchtop analyzer. The Pentra 60 C+ hematology analyzer provides a CBC with 5-part differential result using proprietary technology that ensures an accurate count and differential on the first run. Reduce repeats and reflex to the microscope with Pentra hematology technology.

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TURN SMALL PLACES INTO SMART SPACES

From Abbott

With reduced budgets, shrinking laboratory space and staffing challenges, many laboratories need a solution that lets them work smarter with less. The CELL-DYN Emerald 22 AL is a full performance, automated optical 5-part differential analyzer that delivers smarter results for small to midsize clinical laboratories.

- Compact Design
- Walkaway Functionality
- Ease Of Use
- Smart Safety Features

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Enter Number **3453** in the Search Area

MICROS HEMATOLOGY ANALYZER WITH 3-PART DIFFERENTIAL PLUS THE LITEDM

From HORIBA Medical

Is it viral or bacterial? A CBC with 3-part differential can provide the clues to help distinguish between viral and bacterial infections before you decide to treat. The Micros 60 Hematology analyzer provides a CBC with 3-part Diff result in less than 60 seconds using only 10 µL of sample. Connect to the Lite^{DM} Patient Data Management System for an affordable way to consolidate patient results to one report.

View Brochures, Videos & More at POR.io
Enter Number **3454** in the Search Area





CELL-DYN EMERALD 22 HEMATOLOGY ANALYZER

From Abbott

The CELL-DYN Emerald 22 is a full performance 5-part hematology analyzer for smaller clinical laboratories seeking productivity in smaller spaces.

Benefits:
- Compact Design - To conserve valuable workspace.
- Small and Powerful - Includes a numeric keypad entry, reagent tray, and integrated color touchscreen monitor.
- Easy and Automated - Barcoded reagents and touch-free scheduled daily maintenance, startup and shutdown.
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Designed for labs testing up to 25 samples per day, the Sysmex pocH-100i™ has the smallest footprint of any analyzer on the market. The instrument requires only 15uL of whole blood for reporting of 17 clinical parameters, including a 3-part WBC Differential. It is ideal for urgent care, physician office lab, small clinic, or any outpatient setting where a point of care CBC is needed.

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With its simplified operation, the Sysmex XP-300™ is ideal for clinics and physician office labs. It provides a CBC with 17 different parameters, including a 3-part WBC Differential. The XP-300+M combines the accuracy and reliability of a Sysmex CBC with the agility of Medicus Middleware. Features include EMR connectivity, instrument interfaces and a QC module.

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CELL-DYN **EMERALD 22**

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A suite of harmonized hematology solutions to meet the needs of your laboratory

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HEMATOLOGY

FIRST EVER CLIA WAIVED HEMATOLOGY ANALYZER

From Sysmex

Faster test results, clinical decisions and greater practice efficiency are coming to physicians' offices with the first CLIA-waived CBC analyzer. Hematology diagnostics leader Sysmex is bringing more lab testing to the point of care. One of the most common blood tests can be conducted reliably and accurately on-site, in as few as three minutes. The device's ease of use and innovative technology means in-house staff can operate it in just a few easy steps, without lengthy certification and training. The new Sysmex XW-100 will improve health care efficiency and patient care.

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MULTIPLEX TESTING



3465

BIOFIRE SPOTFIRE

From bioMerieux

bioMérieux knows that an evolving world deserves evolved diagnostics. Our latest innovation, the BIOFIRE® SPOTFIRE® Respiratory Solution, is the first FDA-cleared and CLIA-waived COVID-19 testing solution. The BIOFIRE® SPOTFIRE® System is an easy-to-use system that runs the BIOFIRE® SPOTFIRE® Respiratory (R) Panel. Benefits of the SPOTFIRE Respiratory Solution include: 15 respiratory targets on 1 PCR test with results in about 15 minutes; minimal benchtop space with vertical scalability up to four modules; easy to use with an intuitive user interface.

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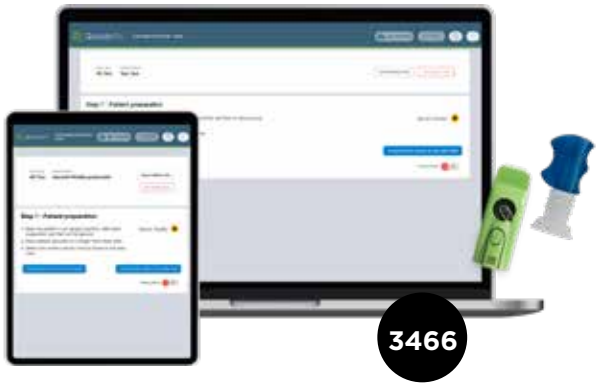
QUANTAFLO® HD

From Semler Scientific

The QuantaFlo® HD application assists in the early detection of Heart Dysfunction (HD). As published in the Journal of Preventive Medicine, QuantaFlo HD showed a statistically significant correlation with cardiac echocardiography, which is a gold standard for diagnosing heart failure.1 The test is highly sensitive, able to detect even asymptomatic HD, and can be performed in the outpatient clinic or the home setting in approximately 5 mins. Results are available immediately and graded as either positive or negative for HD allowing for improved patient selection for echocardiography.

1. Howell, S. C., & Master, R. C. (2023). Clinical Evaluation of Volume Plethysmography as an Aid for Diagnosis of Heart Failure in the Primary Care Setting. Journal of Preventive Medicine, 8(2). https://doi.org/https://preventive-medicine.imedpub.com/clinical-evaluation-of-volume-plethysmography-as-an-aid-for-diagnosis-of-heart-failure-in-the-primary-care-setting.pdf

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PAD TESTING SYSTEMS IDEAL FOR PRIMARY CARE TO VASCULAR SPECIALISTS

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Your Patients Trust YOU To Find Their Peripheral Artery Disease
- High-risk patients include those over 65, diabetics, and smokers.
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- PAD symptoms are often mistaken for arthritis or old age.

The simpleABI Cuff-Link System is Easy to Learn and Use.
- With a push-button remote, automatic calculations, and waveforms, it's incredibly user-friendly.
- Reports are straightforward to save and share since the system is PC-based.

Outstanding Value and Reimbursements
- The system pays for itself in less than a year with just one test per week.
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MD6300 MICRO SPIROMETER
FULL FUNCTION LOW COST SPIROMETER

From Mirco Direct

The Micro Spirometer is the newest offering in the Micro Direct spirometer line. Specifically designed for situations where low cost, precision spirometry measurements are required, the Micro Spirometer is lightweight and portable making it suitable for the physician office. The Micro Spirometer features a large color touch screen that is icon driven. The Micro Spirometer is supplied with Device Studio. A PC software for producing printouts of tests results or for creating PDF reports for attachment to the patients' EMR file.

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3468



3469

MD6800 PNEUMOTRAC SPIROMETER
A POWERFUL SOLUTION FOR PC-BASED SPIROMETRY

From Micro Direct

The Pneumotrac connects to your PC by USB and captures reliable tests results immediately using the Spirotrac 6 software. These results can be printed or shared easily with compatible EMR systems. The Pneumotrac features a highly accurate, extremely stable Fleisch pneumotrach and meets the latest 2019 ATS/ERS standardization of spirometry ensuring testing meets the most up-to-date guidelines. Real-time curves and new animated incentives encourage maximal patient performance and obtain prompt quality feedback using the latest test session/session acceptability, usability and repeatability criteria.

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SOFIA® 2 FLUORESCENT IMMUNOASSAY ANALYZER AND RAPID DIAGNOSTIC TEST KITS

From Quidel

Sofia® 2 Fluorescent Immunoassay Analyzer and Rapid Diagnostic Test Kits Sofia 2 takes rapid testing to a new level. Proven lateral-flow technology and advanced fluorescent chemistry are all integrated into this small benchtop analyzer which can be used in any point-of-care setting. Sofia 2 kits are easy to use and adaptable to any healthcare setting. Excellent performance, objectivity, quality control, LIS capabilities, and an expanding test menu make Sofia 2 the perfect solution for the physician's office laboratory.

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STREP TESTS



3471

OSOM ULTRA PLUS FLU A&B TEST

From Sekisui Diagnostics

Stronger Clinical Performance Takes Lateral Flow Testing To The Next Level. Providing superior rapid results at the point-of-care. Fast, easy, cost effective so you can test and treat in one visit.

- High Performance- Equivalent or exceeding the performance of reader devices, without the need for an instrument
- Results in 10 minutes
- OSOM® Custom Care- Exceptional Support/Training by licensed medical technologists and experienced healthcare professionals
- Made in the USA

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BIOFIRE® FILMARRAY® TORCH

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The BIOFIRE® FILMARRAY® TORCH is a fully integrated, random, and continuous-access system designed to meet your laboratory's syndromic infectious disease testing needs. The benchtop footprint of the BIOFIRE TORCH saves precious lab space, and its scalability meets high throughput demands. BIOFIRE® FILMARRAY® Link Software automatically uploads patient results. Fully compatible with all BIOFIRE® FILMARRAY® Panels intended for use in CLIA-moderate settings, the BIOFIRE TORCH helps you maximize efficiency and productivity.

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TOXICOLOGY



3473

TOXICOLOGY SCREENING SIMPLIFIED ABBOTT'S IMMTOX 270 BENCHTOP ANALYZER NOW WITH 14 ASSAYS CLIA CATEGORIZED AS MODERATE COMPLEXITY

From Abbott

The ImmTox270 benchtop analyzer offers comprehensive toxicology screening solutions for physician offices, treatment centers and independent laboratories.

Broad test menu with over 20 assays to choose from including 14 that are now available as moderately complex.

With complete laboratory solutions from consultation to licensure, and compliance the Abbott Clinical Laboratory Solutions team has you covered.

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TOXICOLOGY

TOXICOLOGY URINE DRUG SCREENING REAGENTS

From Abbott

Prescription drug misuse and illicit drug abuse is a growing public health challenge in this country. Building a test profile that covers highly misused drugs has never been so vital. With over 20 relevant assays to choose from Abbott's suite of Immunalysis reagents allows you to easily screen for relevant substances. Our complete line of assays, calibrators, and controls enables you to implement an efficient drug screening program in office.

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From Carolina Liquid Chemistries

Liquid Chemistries Corp. introduces the Fentanyl Urine Detection Test on CLC's next-generation RYAN™ immunofluorescent analyzer. This FDA cleared and CLIA categorized, moderately complex, compact, point-of-care system detects fentanyl qualitatively in human urine at a cutoff concentration of 1.0 ng/mL. The test can be run in < 6 minutes, produces a chartable result, and is interfaceable. For detailed information, visit carolinachemistries.com/products/fentanyl-urine-detect-on-clc-ryan-analyzer/.

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URINALYSIS

COMPREHENSIVE IN-OFFICE DIABETES TESTING WITH THE DCA VANTAGE® AND CLINITEK STATUS®+ ANALYZERS

From Siemens Healthineers

Siemens Healthineers DCA Vantage® and CLINITEK Status® family of analyzers provide hemoglobin A1c (HbA1c) and albumin-to-creatinine ratio (ACR) testing at the point of care. Meet quality measures for A1c control and kidney disease check in minutes with CLIA-waived HbA1c testing and ACR[1] ratio. Improve patient experience and overall outcome by providing actionable results in minutes.

1. Moderately complex on the DCA Vantage Analyzer. CLIA-waived on the CLINITEK Status+ Analyzer.

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OSOM® BVBLUE®

From Sekisui Diagnostics

The OSOM® BVBLUE® detects elevated vaginal fluid sialidase activity, an enzyme produced by bacterial pathogens associated with bacterial vaginosis including Gardnerella, Bacteroides, Prevotella and Mobiluncus. OSOM® BVBLUE® is more sensitive than Amsel criteria providing physicians with a more accurate diagnosis to treat and minimize serious health consequences such as early spontaneous preterm births and miscarriage.

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OSOM® TRICHOMONAS RAPID TEST

From Sekisui Diagnostics

The OSOM® Trichomonas Rapid Test is intended for the qualitative detection of Trichomonas vaginalis antigens from vaginal swabs or from the saline solution. The OSOM® Trichomonas Rapid Test is a CLIA-waived rapid test available today. OSOM® Trichomonas is more sensitive than wet mount due to the assay being able to detect viable and non-viable organisms which offers significant benefits to the patient and clinician alike.

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ULTRA HCG COMBO TEST

From Sekisui Diagnostics

The OSOM® Ultra hCG Combo test is a simple immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in serum or urine for the early confirmation of pregnancy. Internal studies have confirmed that the OSOM® Ultra hCG Combo test does not have a false negative result from hCG variants providing physicians with a higher level of confidence.

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BRUKINSA: MAKE A POWERFUL IMPACT

IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS

Hemorrhage
Fatal and serious hemorrhage has occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher hemorrhage, including intracranial and gastrointestinal hemorrhage, hematuria and hemothorax have been reported in 3.6% of patients treated with BRUKINSA monotherapy in clinical trials, with fatalities occurring in 0.3% of patients. Bleeding of any grade, excluding purpura and petechiae, occurred in 30% of patients.

Bleeding has occurred in patients with and without concomitant antiplatelet or anticoagulation therapy. Coadministration of BRUKINSA with antiplatelet or anticoagulant medications may further increase the risk of hemorrhage.

Monitor for signs and symptoms of bleeding. Discontinue BRUKINSA if intracranial hemorrhage of any grade occurs. Consider the benefit-risk of withholding BRUKINSA for 3-7 days pre- and post-surgery depending upon the type of surgery and the risk of bleeding.

Infections
Fatal and serious infections (including bacterial, viral, or fungal infections) and opportunistic infections have occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher infections occurred in 24% of patients, most commonly pneumonia (11%), with fatal infections occurring in 2.9% of patients. Infections due to hepatitis B virus (HBV) reactivation have occurred.

Consider prophylaxis for herpes simplex virus, pneumocystis jirovecii pneumonia, and other infections according to standard of care in patients who are at increased risk for infections. Monitor and evaluate patients for fever or other signs and symptoms of infection and treat appropriately.

Cytopenias
Grade 3 or 4 cytopenias, including neutropenia (22%), thrombocytopenia (8%) and anemia (7%) based on laboratory measurements, developed in patients treated with BRUKINSA monotherapy. Grade 4 neutropenia occurred in 11% of patients, and Grade 4 thrombocytopenia occurred in 2.8% of patients.

Monitor complete blood counts regularly during treatment and interrupt treatment, reduce the dose, or discontinue treatment as warranted. Treat using growth factor or transfusions, as needed.

Second Primary Malignancies
Second primary malignancies, including non-skin carcinoma, have occurred in 13% of patients treated with BRUKINSA monotherapy. The most frequent second primary malignancy was non-melanoma skin cancer reported in 7% of patients. Other second primary malignancies included malignant solid tumors (5%), melanoma (1.2%), and hematologic malignancies (0.5%). Advise patients to use sun protection and monitor patients for the development of second primary malignancies.

Cardiac Arrhythmias
Serious cardiac arrhythmias have occurred in patients treated with BRUKINSA. Atrial fibrillation and atrial flutter were reported in 3.7% of 1550 patients treated with BRUKINSA monotherapy, including Grade 3 or higher cases in 1.7% of patients. Patients with cardiac risk factors, hypertension, and acute infections may be at increased risk. Grade 3 or higher ventricular arrhythmias were reported in 0.2% of patients.

Monitor for signs and symptoms of cardiac arrhythmias (e.g., palpitations, dizziness, syncope, dyspnea, chest discomfort), manage appropriately, and consider the risks and benefits of continued BRUKINSA treatment.

Embryo-Fetal Toxicity
Based on findings in animals, BRUKINSA can cause fetal harm when administered to a pregnant woman. Administration of zanubrutinib to pregnant rats during the period of organogenesis caused embryo-fetal toxicity, including malformations at exposures that were 5 times higher than those reported in patients at the recommended dose of 160 mg twice daily. Advise women to avoid becoming pregnant while taking BRUKINSA and for 1 week after the last dose. Advise men to avoid fathering a child during treatment and for 1 week after the last dose. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.

ADVERSE REACTIONS
In this pooled safety population, the most common adverse reactions, including laboratory abnormalities, in ≥30% of patients who received BRUKINSA (N=1550) included decreased neutrophil count (42%), upper respiratory tract infection (39%), decreased platelet count (34%), hemorrhage (30%), and musculoskeletal pain (30%).

THE ONLY BTKi APPROVED ACROSS 4 B-CELL MALIGNANCIES[1-3]

CLL

Superiority across lines of therapy*[1,4,5]

*Superior PFS vs BR in 1L and superior PFS and ORR vs ibrutinib in 2L.

WM

#1 prescribed BTKi in previously untreated patients[6]

MCL

Powerful responses in R/R patients over ~3 years[1,7]

MZL

The only BTKi approved for R/R patients[1-3]

Serious adverse reactions, including fatal events, have occurred with BRUKINSA, including hemorrhage, infections, cytopenias, second primary malignancies, cardiac arrhythmias, and embryo-fetal toxicity. In the (N=1550) pooled safety population, the most common adverse reactions, including laboratory abnormalities, in ≥30% of patients included neutrophil count decreased (42%), upper respiratory tract infection (39%), platelet count decreased (34%), hemorrhage (30%), and musculoskeletal pain (30%).[1]

Find out how BRUKINSA leads the way in BTKis at **BRUKINSA.com**

Enroll patients in the BRUKINSA patient support program at **myBeiGene.com**

DRUG INTERACTIONS

CYP3A Inhibitors: When BRUKINSA is co-administered with a strong CYP3A inhibitor, reduce BRUKINSA dose to 80 mg once daily. For coadministration with a moderate CYP3A inhibitor, reduce BRUKINSA dose to 80 mg twice daily.

CYP3A Inducers: Avoid coadministration with strong or moderate CYP3A inducers. Dose adjustment may be recommended with moderate CYP3A inducers.

SPECIFIC POPULATIONS

Hepatic Impairment: The recommended dose of BRUKINSA for patients with severe hepatic impairment is 80 mg orally twice daily.

INDICATIONS

BRUKINSA is a kinase inhibitor indicated for the treatment of adult patients with:

- Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)
- Waldenström's macroglobulinemia (WM)
- Mantle cell lymphoma (MCL) who have received at least one prior therapy
- Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen

The MCL and MZL indications are approved under accelerated approval based on overall response rate. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

1L=first line; 2L=second line; BR=bendamustine+rituximab; BTKi=Bruton's tyrosine kinase inhibitor; CLL=chronic lymphocytic leukemia; MCL=mantle cell lymphoma; MZL=marginal zone lymphoma; ORR=overall response rate; PFS=progression-free survival; WM=Waldenström's macroglobulinemia.

References: 1. BRUKINSA. Package insert. BeiGene, Ltd; 2023. **2.** CALQUENCE. Package insert. AstraZeneca Pharmaceuticals LP; 2022. **3.** IMBRUVICA. Package insert. Pharmacyclics LLC, Janssen Biotech, Inc; 2023. **4.** Tam CS, Brown JR, Kahl BS, et al. Zanubrutinib versus bendamustine and rituximab in untreated chronic lymphocytic leukaemia and small lymphocytic lymphoma (SEQUOIA): a randomised, controlled, phase 3 trial. *Lancet Oncol*. 2022;23(8):1031-1043. **5.** Brown JR, Eichhorst B, Hillmen P, et al. Zanubrutinib or ibrutinib in relapsed or refractory chronic lymphocytic leukemia. *N Engl J Med*. 2023;388(4):319-332. **6.** Data on file. BeiGene, Ltd. **7.** Song Y, Zhou K, Zou D, et al. Zanubrutinib in relapsed/refractory mantle cell lymphoma: long-term efficacy and safety results from a phase 2 study. *Blood*. 2022;139(21):3148-3158.

Please see Brief Summary of full Prescribing Information on following pages.

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0923-BRU-PRC-213 12/2023

Brukinsa® zanubrutinib 80 mg capsules

BRIEF SUMMARY OF PRESCRIBING INFORMATION
FOR BRUKINSA® (zanubrutinib)
SEE PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Mantle Cell Lymphoma

BRUKINSA is indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.

This indication is approved under accelerated approval based on overall response rate *[see Clinical Studies (14.1)]*. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

1.2 Waldenström's Macroglobulinemia

BRUKINSA is indicated for the treatment of adult patients with Waldenström's macroglobulinemia (WM) *[see Clinical Studies (14.2)]*.

1.3 Marginal Zone Lymphoma

BRUKINSA is indicated for the treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti–CD20-based regimen.

This indication is approved under accelerated approval based on overall response rate *[see Clinical Studies (14.3)]*. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

1.4 Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma

BRUKINSA is indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) *[see Clinical Studies (14.4)]*.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Hemorrhage

Fatal and serious hemorrhage has occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher hemorrhage including intracranial and gastrointestinal hemorrhage, hematuria, and hemothorax was reported in 3.6% of patients treated with BRUKINSA monotherapy in clinical trials, with fatalities occurring in 0.3% of patients. Bleeding of any grade, excluding purpura and petechiae, occurred in 30% of patients.

Bleeding has occurred in patients with and without concomitant antiplatelet or anticoagulation therapy. Coadministration of BRUKINSA with antiplatelet or anticoagulant medications may further increase the risk of hemorrhage.

Monitor for signs and symptoms of bleeding. Discontinue BRUKINSA if intracranial hemorrhage of any grade occurs. Consider the benefit-risk of withholding BRUKINSA for 3-7 days pre and post surgery depending upon the type of surgery and the risk of bleeding.

5.2 Infections

Fatal and serious infections (including bacterial, viral, or fungal infections) and opportunistic infections have occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher infections occurred in 24% of patients, most commonly pneumonia (11%), with fatal infections occurring in 2.9% of patients. Infections due to hepatitis B virus (HBV) reactivation have occurred.

Consider prophylaxis for herpes simplex virus, pneumocystis jirovecii pneumonia, and other infections according to standard of care in patients who are at increased risk for infections. Monitor and evaluate patients for fever or other signs and symptoms of infection and treat appropriately.

5.3 Cytopenias

Grade 3 or 4 cytopenias, including neutropenia (22%), thrombocytopenia (8%), and anemia (7%) based on laboratory measurements, developed in patients treated with BRUKINSA monotherapy *[see Adverse Reactions (6.1)]*. Grade 4 neutropenia occurred in 11% of patients, and Grade 4 thrombocytopenia occurred in 2.8% of patients.

Monitor complete blood counts regularly during treatment and interrupt treatment, reduce the dose, or discontinue treatment as warranted *[see Dosage and Administration (2.4)]*. Treat using growth factor or transfusions, as needed.

5.4 Second Primary Malignancies

Second primary malignancies, including non-skin carcinoma, have occurred in 13% of patients treated with BRUKINSA monotherapy. The most frequent second primary malignancy was non-melanoma skin cancer, reported in 7% of patients. Other second primary malignancies included malignant solid tumors (5%), melanoma (1.2%), and hematologic malignancies (0.5%). Advise patients to use sun protection and monitor patients for the development of second primary malignancies.

5.5 Cardiac Arrhythmias

Serious cardiac arrhythmias have occurred in patients treated with BRUKINSA. Atrial fibrillation and atrial flutter were reported in 3.7% of 1550 patients treated with BRUKINSA monotherapy, including Grade 3 or higher cases in 1.7% of patients. Patients with cardiac risk factors, hypertension, and acute infections may be at increased risk. Grade 3 or higher ventricular arrhythmias were reported in 0.2% of patients.

Monitor for signs and symptoms of cardiac arrhythmias (e.g., palpitations, dizziness, syncope, dyspnea, chest discomfort), manage appropriately *[see Dosage and Administration (2.4)]*, and consider the risks and benefits of continued BRUKINSA treatment.

5.6 Embryo-Fetal Toxicity

Based on findings in animals, BRUKINSA can cause fetal harm when administered to a pregnant woman. Administration of zanubrutinib to pregnant rats during the period of organogenesis caused embryo-fetal toxicity, including malformations at exposures that were 5 times higher than those reported in patients at the recommended dose of 160 mg twice daily. Advise women to avoid becoming pregnant while taking BRUKINSA and for 1 week after the last dose. Advise men to avoid fathering a child during treatment and for 1 week after the last dose. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus *[see Use in Specific Populations (8.1)]*.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are discussed in more detail in other sections of the labeling:

- Hemorrhage *[see Warnings and Precautions (5.1)]*
- Infections *[see Warnings and Precautions (5.2)]*
- Cytopenias *[see Warnings and Precautions (5.3)]*
- Second Primary Malignancies *[see Warnings and Precautions (5.4)]*
- Cardiac Arrhythmias *[see Warnings and Precautions (5.5)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The data in the WARNINGS AND PRECAUTIONS reflect exposure to BRUKINSA as a single-agent in nine clinical trials, administered at 160 mg twice daily in 1445 patients and at 320 mg once daily in 105 patients. Among these 1550 patients, the median duration of exposure was 26 months, 80% of patients were exposed for at least 12 months, and 58% of patients were exposed for at least 24 months.

In this pooled safety population, the most common adverse reactions (≥30%), including laboratory abnormalities, included neutrophil count decreased (42%), upper respiratory tract infection (39%), platelet count decreased (34%), hemorrhage (30%), and musculoskeletal pain (30%).

Mantle Cell Lymphoma (MCL)

The safety of BRUKINSA was evaluated in 118 patients with MCL who received at least one prior therapy in two single-arm clinical trials, BGB-3111-206 [NCT03206970] and BGB-3111-AU-003 [NCT02343120] *[see Clinical Studies (14.1)]*. The median age of patients who received BRUKINSA in studies BGB-3111-206 and BGB-3111-AU-003 was 62 years (range: 34 to 86), 75% were male, 75% were Asian, 21% were White, and 94% had an ECOG performance status of 0 to 1. Patients had a median of 2 prior lines of therapy (range: 1 to 4). The BGB-3111-206 trial required a platelet count ≥75 x 10^9/L and an absolute neutrophil count ≥1 x 10^9/L independent of growth factor support, hepatic enzymes ≤2.5 x upper limit of normal, total bilirubin ≤1.5 x ULN. The BGB-3111-AU-003 trial required a platelet count ≥50 x 10^9/L and an absolute neutrophil count ≥1 x 10^9/L independent of growth factor support, hepatic enzymes ≤3 x upper limit of normal, total bilirubin ≤1.5 x ULN. Both trials required a CLcr ≥30 mL/min. Both trials excluded patients with prior allogeneic hematopoietic stem cell transplant, exposure to a BTK inhibitor, known infection with HIV, and serologic evidence of active hepatitis B or hepatitis C infection, and patients requiring strong CYP3A inhibitors or strong CYP3A inducers. Patients received BRUKINSA 160 mg twice daily or 320 mg once daily. Among patients receiving BRUKINSA, 79% were exposed for 6 months or longer, and 68% were exposed for greater than one year.

Fatal events within 30 days of the last dose of BRUKINSA occurred in 8 (7%) of 118 patients with MCL. Fatal cases included pneumonia in 2 patients and cerebral hemorrhage in one patient.

Serious adverse reactions were reported in 36 patients (31%). The most frequent serious adverse reactions that occurred were pneumonia (11%) and hemorrhage (5%).

Of the 118 patients with MCL treated with BRUKINSA, 8 (7%) patients discontinued treatment due to adverse reactions in the trials. The most frequent adverse reaction leading to treatment discontinuation was pneumonia (3.4%). One (0.8%) patient experienced an adverse reaction leading to dose reduction (hepatitis B).

Table 3 summarizes the adverse reactions in BGB-3111-206 and BGB-3111-AU-003.

Table 3: Adverse Reactions (≥10%) in Patients Receiving BRUKINSA in BGB-3111-206 and BGB-3111-AU-003 Trials

Body System	Adverse Reaction	Percent of Patients (N=118)	
		All Grades %	Grade 3 or Higher %
Infections and infestations	Upper respiratory tract infection[a]	39	0
	Pneumonia[b]	15	10[c]
	Urinary tract infection	11	0.8
Skin and subcutaneous tissue disorders	Rash[d]	36	0
	Bruising[e]	14	0
Gastrointestinal disorders	Diarrhea	23	0.8
	Constipation	13	0
Vascular disorders	Hypertension	12	3.4
	Hemorrhage[f]	11	3.4[c]
Musculoskeletal and connective tissue disorders	Musculoskeletal pain[g]	14	3.4
Respiratory, thoracic and mediastinal disorders	Cough	12	0

[a] Upper respiratory tract infection includes upper respiratory tract infection, upper respiratory tract infection viral.
[b] Pneumonia includes pneumonia, pneumonia fungal, pneumonia cryptococcal, pneumonia streptococcal, atypical pneumonia, lung infection, lower respiratory tract infection, lower respiratory tract infection bacterial, lower respiratory tract infection viral.
[c] Includes fatal adverse reaction.
[d] Rash includes all related terms containing rash.
[e] Bruising includes all related terms containing bruise, bruising, contusion, ecchymosis.
[f] Hemorrhage includes all related terms containing hemorrhage, hematoma.
[g] Musculoskeletal pain includes musculoskeletal pain, musculoskeletal discomfort, myalgia, back pain, arthralgia, arthritis.

Other clinically significant adverse reactions that occurred in <10% of patients with mantle cell lymphoma include major hemorrhage (defined as ≥ Grade 3 hemorrhage or CNS hemorrhage of any grade) (5%), and headache (4.2%).

Table 4: Selected Laboratory Abnormalities[a] (>20%) in Patients with MCL in Studies BGB-3111-206 and BGB-3111-AU-003

Laboratory Parameter	Percent of Patients (N=118)	
	All Grades (%)	Grade 3 or 4 (%)
Hematologic abnormalities		
Neutrophils decreased	45	20
Lymphocytosis[b]	41	16
Platelets decreased	40	7
Hemoglobin decreased	27	6
Chemistry abnormalities		
Blood uric acid increased	29	2.6
ALT increased	28	0.9
Bilirubin increased	24	0.9

[a] Based on laboratory measurements.
[b] Asymptomatic lymphocytosis is a known effect of BTK inhibition.

Waldenström's Macroglobulinemia (WM)

The safety of BRUKINSA was investigated in two cohorts of Study BGB-3111-302 (ASPEN). Cohort 1 included 199 patients with MYD88 mutation (*MYD88^{MUT}*) WM, randomized to and treated with either BRUKINSA (101 patients) or ibrutinib (98 patients). The trial also included a non-randomized arm, Cohort 2, with 26 wild type MYD88 (*MYD88^{WT}*) WM patients and 2 patients with unknown MYD88 status *[see Clinical Studies (14.2)]*.

Among patients who received BRUKINSA, 93% were exposed for 6 months or longer, and 89% were exposed for greater than 1 year.

In Cohort 1 of the ASPEN study safety population (N=101), the median age of patients who received BRUKINSA was 70 years (45-87 years old); 67% were male, 86% were White, 4% were Asian and 10% were not reported (unknown race). In Cohort 2 of the ASPEN study safety population (N=28), the median age of patients who received BRUKINSA was 72 (39-87 years old); 50% were male, 96% were White and 4% were not reported (unknown race).

In Cohort 1, serious adverse reactions occurred in 44% of patients who received BRUKINSA. Serious adverse reactions in >2% of patients included influenza (3%), pneumonia (4%), neutropenia and neutrophil count decreased (3%), hemorrhage (4%), pyrexia (3%), and febrile neutropenia (3%). In Cohort 2, serious adverse reactions occurred in 39% of patients. Serious adverse reactions in >2 patients included pneumonia (14%).

Permanent discontinuation of BRUKINSA due to an adverse reaction occurred in 2% of patients in Cohort 1 and included hemorrhage (1 patient), neutropenia and neutrophil count decreased (1 patient); in Cohort 2, permanent discontinuation of BRUKINSA due to an adverse reaction occurred in 7% of patients and included subdural hemorrhage (1 patient) and diarrhea (1 patient).

Dosage interruptions of BRUKINSA due to an adverse reaction occurred in 32% of patients in Cohort 1 and in 29% in Cohort 2. Adverse reactions which required dosage interruption in >2% of patients included neutropenia, vomiting, hemorrhage, thrombocytopenia, and pneumonia in Cohort 1. Adverse reactions leading to dosage interruption in >2 patients in Cohort 2 included pneumonia and pyrexia.

Dose reductions of BRUKINSA due to an adverse reaction occurred in 11% of patients in Cohort 1 and in 7% in Cohort 2. Adverse reactions which required dose reductions in >2% of patients included neutropenia in Cohort 1. Adverse reaction leading to dose reduction occurred in 2 patients in Cohort 2 (each with one event: diarrhea and pneumonia).

Table 5 summarizes the adverse reactions in Cohort 1 in ASPEN.

Table 5: Adverse Reactions (≥10%) Occurring in Patients with WM Who Received BRUKINSA in Cohort 1

Body System	Adverse Reaction	BRUKINSA (N=101)		Ibrutinib (N=98)	
		All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Infections and infestations	Upper respiratory tract infection[a]	44	0	40	2
	Pneumonia[b]	12	4	26	10
	Urinary tract infection	11	0	13	2
Gastrointestinal disorders	Diarrhea	22	3	34	2
	Nausea	18	0	13	1
	Constipation	16	0	7	0
	Vomiting	12	0	14	1
General disorders	Fatigue[c]	31	1	25	1
	Pyrexia	16	4	13	2
	Edema peripheral	12	0	20	0
Skin and subcutaneous tissue disorders	Bruising[d]	20	0	34	0
	Rash[e]	29	0	32	0
	Pruritus	11	1	6	0
Musculoskeletal and connective tissue disorders	Musculoskeletal pain[f]	45	9	39	1
	Muscle spasms	10	0	28	1
Nervous system disorders	Headache	18	1	14	1
	Dizziness	13	1	12	0
Respiratory, thoracic and mediastinal disorders	Cough	16	0	18	0
	Dyspnea	14	0	7	0
Vascular disorders	Hemorrhage[g]	42	4	43	9
	Hypertension	14	9	19	14

[a] Upper respiratory tract infection includes upper respiratory tract infection, laryngitis, nasopharyngitis, sinusitis, rhinitis, viral upper respiratory tract infection, pharyngitis, rhinovirus infection, upper respiratory tract congestion.
[b] Pneumonia includes lower respiratory tract infection, lung infiltration, pneumonia, pneumonia aspiration, pneumonia viral.
[c] Fatigue includes asthenia, fatigue, lethargy.
[d] Bruising includes all related terms containing bruise, contusion, or ecchymosis.
[e] Rash includes all related terms rash, maculo-papular rash, erythema, rash erythematous, drug eruption, dermatitis allergic, dermatitis atopic, rash pruritic, dermatitis, photodermatoses, dermatitis acneiform, stasis dermatitis, vasculitic rash, eyelid rash, urticaria, skin toxicity.
[f] Musculoskeletal pain includes back pain, arthralgia, pain in extremity, musculoskeletal pain, myalgia, bone pain, spinal pain, musculoskeletal chest pain, neck pain, arthritis, musculoskeletal discomfort.
[g] Hemorrhage includes epistaxis, hematuria, conjunctival hemorrhage, hematoma, rectal hemorrhage, periorbital hemorrhage, mouth hemorrhage, post procedural hemorrhage, hemoptysis, skin hemorrhage, hemorrhoidal hemorrhage, ear hemorrhage, eye hemorrhage, hemorrhagic diathesis, periorbital hematoma, subdural hemorrhage, wound hemorrhage, gastric hemorrhage, lower gastrointestinal hemorrhage, spontaneous hematoma, traumatic hematoma, traumatic intracranial hemorrhage, tumor hemorrhage, retinal hemorrhage, hematochezia, diarrhea hemorrhagic, hemorrhage, melena, post-procedural hematoma, subdural hematoma, anal hemorrhage, hemorrhagic disorder, pericardial hemorrhage, postmenopausal hemorrhage, stoma site hemorrhage, subarachnoid hemorrhage.

Clinically relevant adverse reactions in <10% of patients who received BRUKINSA included localized infection, atrial fibrillation or atrial flutter, and hematuria.

Table 6 summarizes the laboratory abnormalities in ASPEN.

Table 6: Select Laboratory Abnormalities[a] (≥20%) that Worsened from Baseline in Patients with WM Who Received BRUKINSA in Cohort 1

Laboratory Abnormality	BRUKINSA[b]		Ibrutinib[b]	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Hematologic abnormalities				
Neutrophils decreased	50	24	34	9
Platelets decreased	35	8	39	5
Hemoglobin decreased	20	7	20	7
Chemistry abnormalities				
Glucose increased	45	2.3	33	2.3
Creatinine increased	31	1	21	1
Calcium decreased	27	2	26	0
Potassium increased	24	2	12	0
Phosphate decreased	20	3.1	18	0
Urate increased	16	3.2	34	6
Bilirubin increased	12	1	33	1

[a] Based on laboratory measurements.
[b] The denominator used to calculate the rate varied from 86 to 101 based on the number of patients with a baseline value and at least one post-treatment value.

Marginal Zone Lymphoma

The safety of BRUKINSA was evaluated in 88 patients with previously treated MZL in two single-arm clinical studies, BGB-3111-214 and BGB-3111-AU-003 *[see Clinical Studies (14.3)]*. The trials required an absolute neutrophil count ≥1 x 10^9/L, platelet count ≥50 or ≥75 x 10^9/L and adequate hepatic function and excluded patients requiring a strong CYP3A inhibitor or inducer. Patients received BRUKINSA 160 mg twice daily (97%) or 320 mg once daily (3%). The median age in both studies combined was 70 years (range: 37 to 95), 52% were male, 64% were Caucasian and 19% were Asian. Most patients (92%) had an ECOG performance status of 0 to 1. Eighty percent received BRUKINSA for 6 months or longer, and 67% received treatment for more than one year.

Two fatal adverse reactions (2.3%) occurred within 30 days of the last dose of BRUKINSA, including myocardial infarction and a Covid-19–related death.

Serious adverse reactions occurred in 40% of patients. The most frequent serious adverse reactions were pyrexia (8%) and pneumonia (7%).

Adverse reactions lead to treatment discontinuation in 6% of patients, dose reduction in 2.3%, and dose interruption in 34%. The leading cause of dose modification was respiratory tract infections (13%).

Table 7 summarizes selected adverse reactions in BGB-3111-214 and BGB-3111-AU-003.

Table 7: Adverse Reactions Occurring in ≥10% Patients with MZL Who Received BRUKINSA

Body System	Adverse Reaction	BRUKINSA (N=88)	
		All Grades (%)	Grade 3 or 4 (%)
Infections and infestations	Upper respiratory tract infection[a]	26	3.4
	Urinary tract infection[b]	11	2.3
	Pneumonia[c,d]	10	6
Gastrointestinal disorders	Diarrhea[e]	25	3.4
	Abdominal pain[f]	14	2.3
	Nausea	13	0
Skin and subcutaneous tissue disorders	Bruising[g]	24	0
	Rash[h]	21	0
Musculoskeletal and connective tissue disorders	Musculoskeletal pain[i]	27	1.1
Vascular disorders	Hemorrhage[j]	23	1.1
General disorders	Fatigue[k]	21	2.3
Respiratory, thoracic and mediastinal disorders	Cough[l]	10	0

[a] Upper respiratory tract infection includes upper respiratory tract infection, nasopharyngitis, sinusitis, tonsillitis, rhinitis, viral upper respiratory tract infection.
[b] Urinary tract infection includes urinary tract infection, cystitis, Escherichia urinary tract infection, pyelonephritis, cystitis.
[c] Pneumonia includes COVID-19 pneumonia, pneumonia, bronchopulmonary aspergillosis, lower respiratory tract infection, organizing pneumonia.
[d] Includes 2 fatalities from COVID-19 pneumonia.
[e] Diarrhea includes diarrhea and diarrhea hemorrhagic.
[f] Abdominal pain includes abdominal pain, abdominal pain upper, abdominal discomfort.
[g] Bruising includes contusion, ecchymosis, increased tendency to bruise, post procedural contusion.
[h] Rash includes rash, rash maculo-papular, rash pruritic, dermatitis, dermatitis allergic, dermatitis atopic, dermatitis contact, drug reaction with eosinophilia and systemic symptoms, erythema, photosensitivity reaction, rash erythematous, rash papular, seborrheic dermatitis.
[i] Musculoskeletal pain includes back pain, arthralgia, musculoskeletal pain, myalgia, pain in extremity, musculoskeletal chest pain, bone pain, musculoskeletal discomfort, neck pain.
[j] Hemorrhage includes epistaxis, hematuria, hemorrhoidal hemorrhage, hematoma, hemoptysis, conjunctival hemorrhage, diarrhea hemorrhagic, hemorrhage urinary tract, mouth hemorrhage, pulmonary hematoma, subcutaneous hematoma, gingival bleeding, melena, upper gastrointestinal hemorrhage.
[k] Fatigue includes fatigue, lethargy, asthenia.
[l] Cough includes cough and productive cough.

Clinically relevant adverse reactions in <10% of patients who received BRUKINSA included peripheral neuropathy, second primary malignancies, dizziness, edema, headache, petechiae, purpura, and atrial fibrillation or flutter.

Table 8 summarizes select laboratory abnormalities.

Table 8: Select Laboratory Abnormalities (≥20%) that Worsened from Baseline in Patients with MZL

Laboratory Abnormality[a]	BRUKINSA	
	All Grades (%)	Grade 3 or 4 (%)
Hematologic abnormalities		
Neutrophils decreased	43	15
Platelets decreased	33	10
Lymphocytes decreased	32	8
Hemoglobin decreased	26	6
Chemistry abnormalities		
Glucose increased	54	4.6
Creatinine increased	34	1.1
Phosphate decreased	27	2.3
Calcium decreased	23	0
ALT increased	22	1.1

[a] The denominator used to calculate the rate varied from 87 to 88 based on the number of patients with a baseline value and at least one post-treatment value.

Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma

The safety data described below reflect exposure to BRUKINSA (160 mg twice daily) in 675 patients with CLL from two randomized controlled clinical trials *[see Clinical Studies (14.4)]*. The trial required patients to be unsuitable for fludarabine, cyclophosphamide, and rituximab (FCR) therapy defined as age ≥65 years, or age 18 to <65 years with either a total Cumulative Illness Rating Scale (CIRS) >6, creatinine clearance 30 to 69 mL/min, or history of serious or frequent infections. The trial excluded patients with AST or ALT ≥2 times the upper limit of normal (ULN) or bilirubin ≥3 times (ULN) and patients requiring a strong CYP3A inhibitor or inducer.

SEQUOIA

The safety of BRUKINSA monotherapy in patients with previously untreated CLL/SLL was evaluated in a randomized, multicenter, open-label, actively controlled trial *[see Clinical Studies (14.4)]*. Patients without deletion of chromosome 17p13.1 (17p deletion) (Cohort 1) received either BRUKINSA 160 mg twice daily until disease progression or unacceptable toxicity (n=240) or bendamustine plus rituximab (BR) for 6 cycles (n=227). Bendamustine was dosed at 90 mg/m^2/day intravenously on the first 2 days of each cycle, and rituximab was dosed at 375 mg/m^2 on day 1 of Cycle 1 and 500 mg/m^2 on day 1 of Cycles 2 to 6.

Additionally, the same BRUKINSA regimen was evaluated in 111 patients with previously untreated CLL/SLL with 17p deletion in a non-randomized single arm (Cohort 2).

Randomized cohort: Previously untreated CLL/SLL without 17p deletion

In patients with previously untreated CLL/SLL without 17p deletion, the median age was 70, 62% were male, 89% were White, 2% were Asian, and 2% were Black. Most patients (93%) had an ECOG performance status of 0 to 1.

The median duration of exposure to BRUKINSA was 26 months, with 71% exposed for more than 2 years.

Serious adverse reactions occurred in 36% of patients who received BRUKINSA. Serious adverse reactions that occurred in ≥5% of patients were COVID-19, pneumonia, and second primary malignancy (5% each). Fatal adverse reactions occurred in 11 (4.6%) patients with the leading cause of death being COVID-19 (2.1%).

Adverse reactions led to permanent discontinuation of BRUKINSA in 8% of patients, dose reduction in 8%, and dose interruption in 46%. The most common adverse reactions leading to permanent discontinuation were second primary malignancy and COVID-19. The leading causes of dose modification (≥5% of all patients) were respiratory infections (COVID-19, pneumonia) and hemorrhage.

Table 9 summarizes select adverse reactions in this randomized cohort.

Table 9: Adverse Reactions in ≥10% Patients with Previously Untreated CLL/SLL Without 17p Deletion in SEQUOIA

System Organ Class Preferred Term	CLL/SLL without 17p deletion			
	BRUKINSA (N=240)		BR (N=227)	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Musculoskeletal and connective tissue disorders				
Musculoskeletal pain[a]	33	1.7	17	0.4
Infections and infestations				
Upper respiratory tract infection[b]	28	1.3	15	0.9
Pneumonia[c]	13*	5	8†	4
Vascular disorders				
Hemorrhage[d]	27*	4	4	0.4
Hypertension[e]	14	7	5	2.6
Skin and subcutaneous tissue disorders				
Rash[f]	24	1.3	30	5
Bruising[g]	24	0	2.6	0
Respiratory, thoracic and mediastinal disorders				
Cough[e]	15	0	10	0
Gastrointestinal disorders				
Diarrhea	14	0.8	12†	0.9
Constipation	10	0.4	18	0.0
Nausea	10	0	33	1.3
General disorders				
Fatigue[h]	14	1.3	21	1.8
Neoplasms				
Second primary malignancy[i]	13*	6	1.3	0.4
Nervous system disorders				
Headache[e]	12	0	8	0
Dizziness[j]	11	0.8	5	0

* Includes 3 fatal outcomes.
† Includes 2 fatal outcomes.
[a] Musculoskeletal pain: musculoskeletal pain, arthralgia, back pain, pain in extremity, myalgia, neck pain, spinal pain, musculoskeletal discomfort, bone pain.
[b] Upper respiratory tract infection: upper respiratory tract infection, nasopharyngitis, sinusitis, rhinitis, pharyngitis, upper respiratory tract congestion, laryngitis, tonsillitis and upper respiratory tract inflammation, and related terms.
[c] Pneumonia: pneumonia, COVID-19 pneumonia, lower respiratory tract infection, lung infiltration, and related terms including specific types of infection.
[d] Hemorrhage: all terms containing hematoma, hemorrhage, hemorrhagic, and related terms indicative of bleeding.
[e] Includes multiple similar adverse reaction terms.
[f] Rash: Rash, dermatitis, drug eruption, and related terms.
[g] Bruising: all terms containing bruise, bruising, contusion, or ecchymosis.
[h] Fatigue: fatigue, asthenia, and lethargy
[i] Second primary malignancy: includes non-melanoma skin cancer, malignant solid tumors (including lung, renal, genitourinary, breast, ovarian, and rectal), and chronic myeloid leukemia.
[j] Dizziness: dizziness and vertigo.

Other clinically significant adverse reactions occurring in <10% of BRUKINSA recipients in this cohort included COVID-19 (9%), edema (8%), abdominal pain (8%), urinary tract infection (7%), and atrial fibrillation or flutter (3.3%).

Table 10 summarizes select laboratory abnormalities in this cohort.

Table 10: Select Laboratory Abnormalities (≥20%) that Worsened from Baseline in Patients with Previously Untreated CLL/SLL without 17p Deletion in SEQUOIA

Laboratory Abnormality[a]	BRUKINSA		BR	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Hematologic abnormalities				
Neutrophils decreased	37	15	80	53
Hemoglobin decreased	29	2.5	66	8
Platelets decreased	27	1.7	61	11
Leukocytes increased	21[b]	21	0.4	0.4
Chemistry abnormalities				
Glucose increased[c]	55	7	67	10
Creatinine increased	22	0.8	18	0.4
Magnesium increased	22	0	14	0.4
Alanine aminotransferase increased	21	2.1	23	2.2

[a] The denominator used to calculate the rate was 239 in the BRUKINSA arm and 227 in the BR arm, based on the number of patients with a baseline value and at least one post-treatment value. Grading is based on NCI CTCAE criteria.
[b] Lymphocytes increased in 15%.
[c] Non-fasting conditions.

Single-arm cohort: Previously untreated CLL/SLL and 17p deletion

In 111 patients with previously untreated, 17p del CLL/SLL, the median age was 70, 71% were male, 95% were White, and 1% were Asian. Most patients (87%) had an ECOG performance status of 0 to 1. The median duration of exposure to BRUKINSA was 30 months.

Fatal adverse reactions occurred in 3 (2.7%) patients, including pneumonia, renal insufficiency, and aortic dissection (1 patient each).

Serious adverse reactions occurred in 41% of patients treated with BRUKINSA. Serious adverse reactions reported in ≥5% of patients were pneumonia (8%) and second primary malignancy (7%).

Adverse reactions led to treatment discontinuation in 5% of patients, dose reduction in 5%, and dose interruption in 51%. The leading causes of dose modification (≥5% of all patients) were pneumonia, neutropenia, second primary malignancy, and diarrhea.

Table 11 summarizes select adverse reactions in this cohort.

Table 11: Adverse Reactions in ≥10% of Patients with Previously Untreated CLL/SLL and 17p Deletion in SEQUOIA

System Organ Class Preferred Term	CLL/SLL with 17p Deletion	
	BRUKINSA (N=111)	
	All Grades (%)	Grade 3 or 4 (%)
Infections and infestations		
Upper respiratory tract infection[a]	38	0.0
Pneumonia[b]	20*	8
Musculoskeletal and connective tissue disorders		
Musculoskeletal pain[c]	38	2.7
Skin and subcutaneous tissue disorders		
Rash[d]	28	0.0
Bruising[e]	26	0.9
Vascular disorders		
Hemorrhage[f]	28	4.5
Hypertension[g]	11	5.4
Neoplasms		
Second primary malignancy[h]	22†	6
Gastrointestinal disorders		
Diarrhea	18	0.9
Nausea	16	0.0
Constipation	15	0.0
Abdominal pain[g]	12	1.8
Respiratory, thoracic and mediastinal disorders		
Cough[g]	18	0.0
Dyspnea[g]	13	0.0
General disorders and administration site conditions		
Fatigue[i]	14	0.9
Nervous system disorders		
Headache	11	1.8

* Includes 1 fatal outcome.
† Includes non-melanoma skin cancer in 13%.
[a] Upper respiratory tract infection: upper respiratory tract infection, nasopharyngitis, sinusitis, rhinitis, pharyngitis, upper respiratory tract congestion, upper respiratory tract inflammation, viral upper respiratory tract infection, and related terms.
[b] Pneumonia: pneumonia, COVID-19 pneumonia, lower respiratory tract infection, and related terms including specific types of infection.
[c] Musculoskeletal pain: musculoskeletal pain, arthralgia, back pain, pain in extremity, myalgia, neck pain, bone pain.
[d] Rash: Rash, dermatitis, toxic skin eruption, and related terms.
[e] Bruising: all terms containing bruise, bruising, contusion, or ecchymosis.
[f] Hemorrhage: all terms containing hematoma, hemorrhage, hemorrhagic, and related terms indicative of bleeding.
[g] Includes multiple similar adverse reaction terms.
[h] Second primary malignancy: includes non-melanoma skin cancer, malignant solid tumors (including bladder, lung, renal, breast, prostate, ovarian, pelvis, and ureter), and malignant melanoma.
[i] Fatigue: fatigue, asthenia, and lethargy.

Clinically significant adverse reactions occurring in <10% of BRUKINSA recipients in this cohort included urinary tract infection (8%), edema (7%), atrial fibrillation or flutter (4.5%), and COVID-19 (3.6%).

Table 12 summarizes select laboratory abnormalities in this cohort.

Table 12: Select Laboratory Abnormalities (≥20%) that Worsened from Baseline in Patients with Previously Untreated CLL/SLL and 17p Deletion in SEQUOIA

Laboratory Abnormality[a]	BRUKINSA	
	All Grades (%)	Grade 3 or 4 (%)
Hematologic abnormalities		
Neutrophils decreased	42	19[b]
Hemoglobin decreased	26	3.6
Platelets decreased	23	0.9
Chemistry abnormalities		
Glucose increased[c]	52	6
Magnesium increased	31	0
Creatinine increased	27	0.9

[a] The denominator used to calculate the rate varied from 110 to 111 based on the number of patients with a baseline value and at least one post-treatment value. Grading is based on NCI CTCAE criteria.
[b] Grade 4, 9%.
[c] Non-fasting conditions.

ALPINE

The safety of BRUKINSA monotherapy was evaluated in patients with previously treated CLL/SLL in a randomized, multicenter, open-label, actively controlled trial *[see Clinical Studies (14.4)]*. In ALPINE, 324 patients received BRUKINSA monotherapy, 160 mg orally twice daily and 324 patients received ibrutinib monotherapy, 420 mg orally daily until disease progression or unacceptable toxicity.

In ALPINE, the median duration of exposure was 24 months for BRUKINSA. Adverse reactions leading to death in the BRUKINSA arm occurred in 24 (7%) patients. Adverse reactions leading to death that occurred in >1% of patients were pneumonia (2.8%) and COVID-19 infection (1.9%).

One hundred and four patients in the BRUKINSA arm (32%) reported ≥1 serious adverse reaction. Serious adverse reactions occurring in ≥5% of patients were pneumonia (10%), COVID-19 (7%), and second primary malignancies (5%).

Adverse reactions led to treatment discontinuation in 13% of patients, dose reduction in 11%, and dose interruption in 42%. The leading cause of treatment discontinuation was pneumonia. The leading causes of dose modification (≥5% of all patients) were respiratory infections (COVID-19, pneumonia) and neutropenia.

Table 13 summarizes select adverse reactions in ALPINE.

Table 13: Adverse Reactions in ≥10% of Patients with Relapsed or Refractory CLL/SLL Who Received BRUKINSA in ALPINE

System Organ Class Preferred Term	BRUKINSA (N=324)		Ibrutinib (N=324)	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Infections and infestations				
Upper respiratory tract infection[a]	27	1.2	22	1.2
Pneumonia[b]	18*	9	19†	11
COVID-19[c]	14*	7	10†	4.6
Musculoskeletal and connective tissue disorders				
Musculoskeletal pain[d]	26	0.6	28	0.6
Vascular disorders				
Hemorrhage[e]	24*	2.5	26†	3.7
Hypertension[f]	19	13	20	13
Skin and subcutaneous tissue disorders				
Rash[g]	20	1.2	21	0.9
Bruising[h]	16	0.0	14	0.0
Gastrointestinal disorders				
Diarrhea	14	1.5	22	0.9
General disorders				
Fatigue[i]	13	0.9	14	0.9
Respiratory, thoracic and mediastinal disorders				
Cough[f]	11	0.3	11	0.0
Nervous system disorders				
Dizziness[f]	10	0.0	7	0.0

* Includes fatal outcomes: pneumonia (9 patients), COVID-19 (8 patients), and hemorrhage (1 patient).
† Includes fatal outcomes: pneumonia (10 patients), COVID-19 (9 patients), and hemorrhage (2 patients).
[a] Upper respiratory tract infection: upper respiratory tract infection, sinusitis, pharyngitis, rhinitis, nasopharyngitis, laryngitis, tonsillitis, and related terms.
[b] Pneumonia: Pneumonia, COVID-19 pneumonia, lower respiratory tract infection, lung infiltration, and related terms including specific types of infection.
[c] COVID-19: COVID-19, COVID-19 pneumonia, post-acute COVID-19 syndrome, SARS-CoV-2 test positive.
[d] Musculoskeletal pain: musculoskeletal pain, arthralgia, back pain, pain in extremity, myalgia, neck pain, spinal pain, bone pain, and musculoskeletal discomfort.
[e] Hemorrhage: all terms containing hematoma, hemorrhage, hemorrhagic, and related terms indicative of bleeding.
[f] Includes multiple similar adverse reaction terms.
[g] Rash: Rash, Dermatitis, and related terms.
[h] Bruising: all terms containing bruise, bruising, contusion, or ecchymosis.
[i] Fatigue: asthenia, fatigue, lethargy.

Clinically relevant adverse reactions in <10% of patients who received BRUKINSA included urinary tract infection (9%), supraventricular arrhythmias (9%) including atrial fibrillation or flutter (4.6%), abdominal pain (8%), headache (8%), pruritus (6.2%), constipation (5.9%), and edema (4.6%).

Table 14 summarizes select laboratory abnormalities in ALPINE.

Table 14: Select Laboratory Abnormalities (≥20%) that Worsened from Baseline in Patients Who Received BRUKINSA in ALPINE

Laboratory Abnormality[a]	BRUKINSA		Ibrutinib	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Hematologic abnormalities				
Neutrophils decreased	43	15	33	16
Hemoglobin decreased	28	4	32	3.7
Lymphocytes increased	24	19	26	19
Platelets decreased	22	4	24	3.4
Chemistry abnormalities				
Glucose increased	52	5	29	2.8
Creatinine increased	26	0.0	23	0.0
Phosphate decreased	21	2.5	13	2.2
Calcium decreased	21	0.6	29	0.0

[a] The denominator used to calculate the rate was 321 in the BRUKINSA arm, and varied from 320 to 321 in the ibrutinib arm, based on the number of patients with a baseline value and at least one post-treatment value. Grading is based on NCI CTCAE criteria.

7 DRUG INTERACTIONS

7.1 Effect of Other Drugs on BRUKINSA

Table 15: Drug Interactions that Affect Zanubrutinib

Moderate and Strong CYP3A Inhibitors	
Clinical Impact	• Coadministration with a moderate or strong CYP3A inhibitor increases zanubrutinib C_{max} and AUC *[see Clinical Pharmacology (12.3)]* which may increase the risk of BRUKINSA toxicities.
Prevention or management	• Reduce BRUKINSA dosage when coadministered with moderate or strong CYP3A inhibitors *[see Dosage and Administration (2.3)]*.
Moderate and Strong CYP3A Inducers	
Clinical Impact	• Coadministration with a moderate or strong CYP3A inducer decreases zanubrutinib C_{max} and AUC *[see Clinical Pharmacology (12.3)]* which may reduce BRUKINSA efficacy.
Prevention or management	• Avoid coadministration of BRUKINSA with strong CYP3A inducers *[see Dosage and Administration (2.3)]*. • Avoid coadministration of BRUKINSA with moderate CYP3A4 inducers *[see Dosage and Administration (2.3)]*. If these inducers cannot be avoided, increase BRUKINSA dosage to 320 mg twice daily *[see Dosage and Administration (2.3)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Based on findings in animals, BRUKINSA can cause fetal harm when administered to pregnant women. There are no available data on BRUKINSA use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. In animal reproduction studies, oral administration of zanubrutinib to pregnant rats during the period of organogenesis was associated with fetal heart malformation at approximately 5-fold human exposures *(see Data)*. Women should be advised to avoid pregnancy while taking BRUKINSA. If BRUKINSA is used during pregnancy, or if the patient becomes pregnant while taking BRUKINSA, the patient should be apprised of the potential hazard to the fetus.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data

Animal Data

Embryo-fetal development toxicity studies were conducted in both rats and rabbits. Zanubrutinib was administered orally to pregnant rats during the period of organogenesis at doses of 30, 75, and 150 mg/kg/day. Malformations in the heart (2 or 3-chambered hearts) were noted at all dose levels in the absence of maternal toxicity. The dose of 30 mg/kg/day is approximately 5 times the exposure (AUC) in patients receiving the recommended dose of 160 mg twice daily.

Administration of zanubrutinib to pregnant rabbits during the period of organogenesis at 30, 70, and 150 mg/kg/day resulted in post-implantation loss at the highest dose. The dose of 150 mg/kg is approximately 32 times the exposure (AUC) in patients at the recommended dose and was associated with maternal toxicity.

In a pre and postnatal developmental toxicity study, zanubrutinib was administered orally to rats at doses of 30, 75, and 150 mg/kg/day from implantation through weaning. The offspring from the middle and high dose groups had decreased body weights preweaning, and all dose groups had adverse ocular findings (e.g., cataract, protruding eye). The dose of 30 mg/kg/day is approximately 5 times the AUC in patients receiving the recommended dose.

8.2 Lactation

Risk Summary

There are no data on the presence of zanubrutinib or its metabolites in human milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions from BRUKINSA in a breastfed child, advise lactating women not to breastfeed during treatment with BRUKINSA and for two weeks following the last dose.

8.3 Females and Males of Reproductive Potential

BRUKINSA can cause embryo-fetal harm when administered to pregnant women *[see Use in Specific Populations (8.1)]*.

Pregnancy Testing

Pregnancy testing is recommended for females of reproductive potential prior to initiating BRUKINSA therapy.

Contraception

Females

Advise female patients of reproductive potential to use effective contraception during treatment with BRUKINSA and for 1 week following the last dose of BRUKINSA. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be informed of the potential hazard to a fetus.

Males

Advise men to avoid fathering a child while receiving BRUKINSA and for 1 week following the last dose of BRUKINSA.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

Of the 1550 patients with MCL, MZL, WM, and CLL/SLL in clinical studies with BRUKINSA, 61% were ≥65 years of age, and 22% were ≥75 years of age. Patients ≥65 years of age had numerically higher rates of Grade 3 or higher adverse reactions and serious adverse reactions (63% and 47%, respectively) than patients <65 years of age (57% and 36%, respectively). No overall differences in effectiveness were observed between younger and older patients.

8.6 Renal Impairment

No dosage modification is recommended in patients with mild, moderate, or severe renal impairment (CLcr ≥15 mL/min, estimated by Cockcroft-Gault). Monitor for BRUKINSA adverse reactions in patients on dialysis *[see Clinical Pharmacology (12.3)]*.

8.7 Hepatic Impairment

Dosage modification of BRUKINSA is recommended in patients with severe hepatic impairment *[see Dosage and Administration (2.2)]*. The safety of BRUKINSA has not been evaluated in patients with severe hepatic impairment. No dosage modification is recommended in patients with mild to moderate hepatic impairment. Monitor for BRUKINSA adverse reactions in patients with hepatic impairment *[see Clinical Pharmacology (12.3)]*.

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