Welcome to Verzenio





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Personalized support that's here for you

Find out how to enroll on page 15

The Verzenio Continuous Care Team is not made up of medical professionals. Your doctor is your source for medical advice.



About Verzenio

Whether you're newly diagnosed or just starting treatment, this brochure can help you learn more about Verzenio.

Verzenio-an everyday* treatment for a relentless disease

*150 mg or 200 mg orally twice a day, as directed by your doctor.

Verzenio is a prescription medicine used to treat a type of breast cancer. It is a medicine you can take if:

- You have a type of breast cancer called HR+/HER2– (hormone receptor positive/human epidermal growth factor receptor 2 negative) and the cancer has spread to other parts of the body (metastasized)
- Verzenio is given in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women, in combination with fulvestrant in women whose disease has progressed after hormonal therapy, or alone in women whose disease has progressed after hormone therapy and prior chemotherapy

It is not known if Verzenio is safe and effective in children.

SELECT SAFETY INFORMATION

Verzenio may cause serious side effects, including:

Diarrhea is common with Verzenio, may be severe and may cause dehydration or infection. The most common time to develop diarrhea is during the first month of Verzenio treatment. Your doctor may stop your treatment, lower your dose, or tell you to wait to begin your treatment cycle if you have diarrhea.

At the first sign of loose stools, tell your doctor. You may be advised to start taking an antidiarrheal medicine (such as loperamide) and drink more fluids.

About Verzenio



What is Verzenio?

Verzenio is a targeted treatment known as a CDK4 & 6 inhibitor.

Verzenio is not chemotherapy.

Verzenio is a prescription medicine used to treat a type of breast cancer. It is a medicine you can take if you have a type of breast cancer called HR+/HER2- and the cancer has spread to other parts of the body (metastasized).

How Verzenio is given

- In combination with an aromatase inhibitor (AI) as initial endocrine-based therapy for the treatment of postmenopausal women
- In combination with fulvestrant in women whose disease has progressed after hormonal therapy
- Alone in women whose disease has progressed after hormone therapy and prior chemotherapy

It is not known if Verzenio is safe and effective in children.

CDK4 & 6=cyclin-dependent kinases 4 and 6. HER2-=human epidermal growth factor receptor 2–negative. HR+=hormone receptor–positive.

How Verzenio works

Verzenio targets breast cancer cells where they grow and divide

- Verzenio is in a class of drugs known as CDK4 & 6 inhibitors. CDK4 & 6 are proteins that control how fast cells grow and divide
- These proteins are found on both normal and cancer cells. They become overactive in metastatic breast cancer, causing cells to grow and divide uncontrollably. This leads to the spread of cancer
- Verzenio interrupts these proteins and cells just as they are deciding to grow and divide. It slows down cancer cell growth and division, causing cancer cells to become inactive or even die
- In preclinical studies, continuous exposure to Verzenio put the brakes on CDK4 & 6 proteins, which delayed cancer cells from growing and dividing

How is Verzenio different?

Verzenio is taken differently—it's the first and only CDK4 & 6 inhibitor that can be taken every day, twice a day*

Verzenio is a CDK4 & 6 inhibitor. It is the first and only oral tablet of its kind that can be taken every day for the treatment of HR+, HER2– metastatic breast cancer.

*150 mg or 200 mg orally twice a day, as directed by your doctor.

SELECT SAFETY INFORMATION

Verzenio may cause serious side effects, including:

Low white blood cell counts (neutropenia) are common with Verzenio and may cause serious infections that can lead to death. Your doctor should check your white blood cell counts before and during treatment. Tell your doctor right away if you have fever or chills.



Dosing

Learn more about how to take Verzenio.

VERZENIO + AN AROMATASE INHIBITOR (AI)*

VERZENIO + FULVESTRANT⁺

1 150-mg tablet by mouth in the morning

1 150-mg tablet by mouth in the evening

You will receive 4 individual packs,[‡] each containing 0.0.0.0 your dose of 150-mg 0 0 0 0 tablets for 7 days

1 150-mg tablet by	
mouth in the morning	

1 150-mg tablet by mouth in the evening

You will receive 4 individual packs,[‡] each containing 0000 your dose of 150-mg 0 0 0 0 tablets for 7 days

VERZENIO BY ITSELF

1 200-mg tablet by mouth in the morning

1 200-mg tablet by mouth in the evening

You will receive 4 individual packs,[‡] each containing 0 0 0 0 your dose of 200-mg 0 0 0 0 tablets for 7 days

Try to establish a routine of taking your morning and evening doses at about the same time each day.

- Do not stop taking Verzenio or change the dose without talking to your doctor
- Multiple tablet strengths (50 mg, 100 mg, 150 mg, and 200 mg) allow your doctor to make dose adjustments based on your tolerance
- If you need to reduce your dose due to tolerability, Verzenio is approved to be dosed as low as 50 mg twice daily, as directed by your doctor
- No matter what dose you are prescribed, you will take 1 tablet, 2 times a day, unless your doctor tells you otherwise

*The recommended dose of an AI is 1 tablet taken by mouth once daily. The recommended doses for letrozole and anastrozole are 2.5 mg and 1 mg, respectively.

[†]The recommended starting dose of fulvestrant is 500 mg administered on days 1, 15, and

29 for the first month and once monthly thereafter.

[‡]Each of these packs includes 14 individual tablets.

SELECT SAFETY INFORMATION

Verzenio may cause serious side effects, including:

Verzenio may cause severe or life-threatening inflammation (swelling) of the lungs during treatment that can lead to death. Tell your healthcare provider right away if you have any new or worsening symptoms, including:

- Trouble breathing or shortness of breath
- Cough with or without mucus
- Chest pain





What should I do if I miss a dose or get sick after taking a dose?

- If you miss a dose of Verzenio or get sick after taking a dose, take your next dose at your regular time. Do not take an extra dose of Verzenio to make up for any dose you may have missed
- For example, if you forget to take your morning dose, then you should only take your regular evening dose rather than doubling it

How should I take Verzenio?

- Swallow the prescribed number of Verzenio tablets whole. Do not chew, crush, or split before swallowing
- You can take Verzenio with or without food
- Avoid grapefruit and grapefruit products while taking Verzenio. Grapefruit may increase the amount of Verzenio in your blood

Can I take other medicines with Verzenio?

- Verzenio and certain other medicines can affect each other, causing serious side effects or changing the effect of Verzenio or other medications
- Before starting any medication, make sure you talk to your doctor about all your other medications. Some examples include prescription and over-the-counter medicines, vitamins, and herbal supplements. Your doctor may need to change your dose

If you have questions about Verzenio or need more information on how to take it, you should talk to your doctor. You can also call us at 1-844-VERZENIO (1-844-837-9364).



If you take more Verzenio than was prescribed, call your doctor or go to the nearest hospital emergency room right away

SELECT SAFETY INFORMATION

Verzenio may cause serious side effects, including:

Verzenio can cause liver problems. Tell your doctor right away if you have any of the following signs or symptoms of liver problems:

- Feeling very tired
- Pain on the upper right side of your stomach area (abdomen)
- Loss of appetite
- Bleeding or bruising more easily than normal



/erzenio + an aromatase inhibitor (AI)

Explore the effectiveness and side effects of Verzenio + an AI.

Verzenio was studied in combination with an AI as initial endocrine-based therapy in 493 postmenopausal women with newly diagnosed, hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic breast cancer. In the study, 328 patients were treated with Verzenio + an AI and 165 were treated with an AI alone.



LIVE LONGER WITHOUT CANCER GETTING WORSE Verzenio + an AI delayed disease progression for over 2 years

(a median of 28.2 months) vs 14.8 months with an AI alone



MORE THAN HALF OF WOMEN SAW THEIR TUMORS SHRINK 55.4% of women on Verzenio + an AI saw their tumors shrink vs 40.2% on an AI alone



COMPLETE RESPONSE: NO DETECTABLE SIGNS OF CANCER 3.4% of women on Verzenio + an Al had a

complete response vs 0% with an Al alone

TUMOR SHRINKAGE OF 30% or more

PARTIAL RESPONSE: TUMOR SHRINKAGE OF 30% OR MORE 52.1% of women on Verzenio + an AI had a partial response vs 40.2% with an AI alone

Clinical trials are still ongoing to see if there is an overall survival benefit with Verzenio + an AI.

SELECT SAFETY INFORMATION

Verzenio may cause serious side effects, including:

Verzenio may cause blood clots in your veins or lungs. These may be serious and have led to death. Tell your doctor if you have the following signs and symptoms of a blood clot:

- Pain or swelling in your arms or legs
- Shortness of breath •

Fast breathing

Fast heart rate

- Chest pain
- Please see Purpose and Safety Summary on pages 17-18.



Verzenio + an Al

Side effects

Most common side effects

- Diarrhea
- Low white blood cell count (leukopenia/neutropenia)
- Infections
- Nausea
- Low red blood cell count (anemia)

- Vomiting
- Hair loss or thinning (alopecia)
- Decreased appetite
- Tiredness
- Abdominal pain

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Verzenio. For more information, ask your doctor or pharmacist.

TO LEARN MORE ABOUT ADDRESSING SIDE EFFECTS, TURN TO PAGES 13-14

SELECT SAFETY INFORMATION

Verzenio may cause serious side effects, including:

Verzenio can harm your unborn baby. Use effective birth control during treatment and for at least 3 weeks after the last dose of Verzenio and do not breastfeed during treatment with Verzenio and for at least 3 weeks after your last dose. Verzenio may affect the ability of males to father a child.



Verzenio + fulvestrant

Explore the effectiveness and side effects of Verzenio + fulvestant.

Verzenio was studied in a clinical trial of 669 women with hormone receptor–positive (HR+), human epidermal growth factor receptor 2–negative (HER2–) metastatic breast cancer, whose disease had progressed after hormone treatment: 446 patients were treated with Verzenio + fulvestrant, and 223 were treated with fulvestrant alone.



WOMEN LIVED LONGER ON VERZENIO + FULVESTRANT

In the clinical study, women taking Verzenio + fulvestrant lived for a median of 46.7 months vs 37.3 months on fulvestrant alone



MORE TIME WITHOUT DISEASE PROGRESSION

In the same study, Verzenio + fulvestrant delayed disease progression for a median of 16.4 months vs 9.3 months with fulvestrant alone



TWICE AS MANY WOMEN SAW THEIR TUMORS SHRINK

48.1% of patients on Verzenio + fulvestrant saw their tumors shrink vs 21.3% with fulvestrant alone

NO DETECTABLE SIGNS of cancer

COMPLETE RESPONSE: NO DETECTABLE SIGNS OF CANCER

In a clinical study, 3.5% of women on Verzenio + fulvestrant had a complete response, or no detectable sign of cancer, vs 0% with fulvestrant alone

SELECT SAFETY INFORMATION

Common side effects

The most common side effects of Verzenio include:

- Nausea
- Infections
- Low red blood cell counts (anemia)
- Decreased appetite
- Headache
- Hair thinning or hair loss (alopecia)

These are not all the possible side effects of Verzenio.

TUMOR SHRINKAGE OF **30%** or more

PARTIAL RESPONSE: TUMOR SHRINKAGE OF 30% OR MORE

In the same study, 44.7% of women on Verzenio + fulvestrant had a partial response with tumor shrinkage of 30% or more vs 21.3% with fulvestrant alone

- Abdominal pain
- Tiredness
- Low white blood cell counts (leukopenia)
- Vomiting
- Low platelet counts (thrombocytopenia)



Verzenio + fulvestrant

Side effects

Most common side effects

- Diarrhea
- Nausea
- Infections
- Low white blood cell count (leukopenia/neutropenia)
- Abdominal pain

- Low red blood cell count (anemia)
- Tiredness
- Decreased appetite
- Vomiting
- Headache

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Verzenio. For more information, ask your doctor or pharmacist.

> TO LEARN MORE ABOUT ADDRESSING SIDE EFFECTS, TURN TO PAGES 13-14

SELECT SAFETY INFORMATION

Before using

Before you use Verzenio, tell your doctor:

- If you have fever, chills, or other signs of infection
- Have liver or kidney problems
- About all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your doctor if you take a medicine that contains ketoconazole. Avoid grapefruit products while taking Verzenio. Grapefruit may increase the amount of Verzenio in your blood



TUMOR

Verzenio by itself

Explore the effectiveness and side effects of Verzenio by itself.

Verzenio was studied in 132 adult patients with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic breast cancer who had progressed on or after prior hormone treatments, a taxane, and 1 or 2 chemotherapy regimens in the metastatic setting. All patients were treated with only Verzenio.

VERZENIO SHRINKS TUMORS AND DELAYS THE SPREAD OF CANCER

When other advanced or metastatic breast cancer treatments (hormonal treatments and prior chemotherapy) stopped working, Verzenio helped delay the growth and spread of cancer in a clinical study.

SHRINKAGE OF 19.7% of women taking Verzenio alone saw their tumors shrink by 30% or more. In the same study, an independent **30**% or more review found similar results (17.4% of women)

SELECT SAFETY INFORMATION

Verzenio may cause serious side effects, including:

Diarrhea is common with Verzenio, may be severe and may cause dehydration or infection. The most common time to develop diarrhea is during the first month of Verzenio treatment. Your doctor may stop your treatment, lower your dose, or tell you to wait to begin your treatment cycle if you have diarrhea.

At the first sign of loose stools, tell your doctor. You may be advised to start taking an antidiarrheal medicine (such as loperamide) and drink more fluids.



Verzenio by itself

Side effects

Most common side effects

- Diarrhea
- Tiredness
- Nausea
- Decreased appetite
- Abdominal pain
- Low white blood cell count (neutropenia)

- Vomiting
- Infections
- Low red blood cell count (anemia)
- Headache
- Low platelet count (thrombocytopenia)

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Verzenio. For more information, ask your doctor or pharmacist.

TO LEARN MORE ABOUT ADDRESSING SIDE EFFECTS, TURN TO PAGES 13-14

SELECT SAFETY INFORMATION

Verzenio may cause serious side effects, including:

Low white blood cell counts (neutropenia) are common with Verzenio and may cause serious infections that can lead to death. Your doctor should check your white blood cell counts before and during treatment. Tell your doctor right away if you have fever or chills.



Addressing side effects

Learn how to address some common side effects.

Verzenio may cause side effects, including diarrhea, low white blood cell counts, severe inflammation of the lungs, liver problems, or blood clots. Verzenio can harm your unborn baby.

These are not all the possible side effects of Verzenio. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call **1-800-FDA-1088**.

You may also report side effects to Eli Lilly and Company at 1-800-545-5979.

Addressing diarrhea

The first step to managing side effects is to know what to expect.

Diarrhea is one of the most common side effects with Verzenio. Read on to learn more about how to **EXPECT**, **PLAN**, and **ACT** if you experience diarrhea while taking Verzenio.

Diarrhea can be managed with the appropriate steps, so EXPECT, PLAN, and ACT.

EXPECT: DIARRHEA IS A COMMON SIDE EFFECT

Diarrhea is a common side effect with Verzenio and may sometimes be severe, but you and your doctor can take steps to manage it. If diarrhea occurs, it will most likely happen in the first week. You should be on the lookout for cramping or frequent, loose, or watery stools.

PLAN: PLAN AHEAD OF TIME

It is important to plan ahead of time with your doctor. Make sure you have an over-the-counter anti-diarrheal medicine, such as loperamide (also known as Imodium[®]) available at home before you start taking Verzenio.

ACT: IMMEDIATE 24-HOUR ACTION PLAN

If you begin experiencing diarrhea, it is very important that you take action immediately at the first signs of symptoms. The best way to manage diarrhea is to start an anti-diarrheal at the first sign and call your doctor, who may make a dose change.

SELECT SAFETY INFORMATION

Verzenio may cause serious side effects, including:

Verzenio may cause severe or life-threatening inflammation (swelling) of the lungs during treatment that can lead to death. Tell your healthcare provider right away if you have any new or worsening symptoms, including:

- Trouble breathing or shortness of breath
- Cough with or without mucus
- Chest pain



Immediate 24-hour action plan



STEP 1: Start an anti-diarrheal and call your doctor

If you are experiencing diarrhea, you need to start taking an anti-diarrheal as directed on the packaging and call your doctor or nurse immediately so they are aware and can help you manage the diarrhea.



STEP 2: Stay hydrated and drink clear fluids

Drink at least 8-10 glasses of clear fluids in the first 24 hours you experience symptoms (and continue any day you experience diarrhea) to avoid dehydration.



STEP 3: Watch for improvement and follow up with your doctor

Ideally, the anti-diarrheal will be able to help resolve your symptoms, but **if symptoms continue after the first 24 hours, you need to talk to your doctor or nurse that day**. He or she may consider adjusting your dose, with the ultimate goal of finding which dose is right for you. Verzenio is effective at different doses, so it is important to find what dose is right for your body.



MONITORING BLOOD COUNTS AND LIVER FUNCTION

Some patients experienced low white blood cell counts (neutropenia) and/or liver problems. Your doctor will do blood tests to monitor your blood cell counts and to check for liver problems before and during treatment.

SELECT SAFETY INFORMATION

Verzenio may cause serious side effects, including:

Verzenio can cause liver problems. Tell your doctor right away if you have any of the following signs or symptoms of liver problems:

- Feeling very tired
- Pain on the upper right side of your stomach area (abdomen)
- Loss of appetite
- Bleeding or bruising more easily than normal



Savings & support

See how you can save on Verzenio and get support along the way.

Personalized care that's here for you

Verzenio Continuous Care[™]



We created the Verzenio Continuous Care program to give you personalized support and help you have a positive experience while taking Verzenio. Your Verzenio Continuous Care Team* will serve as your dedicated partner throughout every stage of your treatment.

Through 1-on-1 check-ins, your Verzenio Continuous Care Team can support you by:

- Navigating you through the insurance process
- Identifying savings opportunities
- Helping you understand what to expect with Verzenio
- Answering questions you may have about Verzenio



*The Verzenio Continuous Care Team is not made up of medical professionals. Your doctor is your source for medical advice.



Savings card

Paying for treatment shouldn't be an additional concern for you and your loved ones, so we've created the Verzenio Savings Card,* which may help you manage treatment costs.



Pay as little as \$0 a month when commercially insured*

*Terms and conditions: Offer good for up to 12 months until 12/31/2021. \$0 monthly offer for commercially insured patients with insurance provider coverage and a valid prescription for a 28-day supply of Verzenio. Subject to a monthly cap of wholesale acquisition cost plus usual and customary pharmacy charges and a separate \$25,000 maximum annual cap. Patient is responsible for any applicable taxes, fees, or amounts exceeding monthly or annual caps. This offer is invalid for patients without commercial drug insurance or those whose prescription claims are eligible to be reimbursed, in whole or in part, by any governmental program, including, without limitation, Medicaid, Medicare, Medicare Part D, Medigap, DOD, VA, TRICARE®/CHAMPUS, or any state patient or pharmaceutical assistance program. Offer void where prohibited by law and subject to change or discontinue without notice. Card activation is required. Subject to additional terms and conditions, which can be found at verzenio.com.

Visit **verzenio.com** for more information on the Verzenio Savings Card



PURPOSE AND SAFETY SUMMARY

Important Facts About Verzenio® (ver-ZEN-ee-oh). It is also known as abemaciclib.

Verzenio is a prescription medicine used to treat a type of breast cancer. It is a medicine you can take if:

- You have a type of breast cancer called HR+/HER2- (hormone receptor positive/human epidermal growth factor receptor 2 negative) and the cancer has spread to other parts of the body (metastasized)
- Verzenio is given along with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women, along with fulvestrant in women whose disease has progressed after hormonal therapy, or by itself in adults whose disease has progressed after hormone therapy and prior chemotherapy

It is not known if Verzenio is safe and effective in children.

Warnings

Verzenio may cause serious side effects, including:

Diarrhea is common with Verzenio, may be severe and may cause dehydration or infection. The most common time to develop diarrhea is during the first month of Verzenio treatment. Your doctor may stop your treatment, lower your dose, or tell you to wait to begin your treatment cycle if you have diarrhea.

At the first sign of loose stools, tell your doctor. You may be advised to start taking an antidiarrheal medicine (such as loperamide) and drink more fluids.

Low white blood cell counts (neutropenia) are common with Verzenio and may cause serious infections that can lead to death. Your doctor should check your white blood cell counts before and during treatment. Tell your doctor right away if you have fever or chills.

Verzenio may cause severe or life-threatening inflammation (swelling) of the lungs during treatment that can lead to death. Tell your healthcare provider right away if you have any new or worsening symptoms, including:

- Trouble breathing or shortness of breath
- Cough with or without mucus
- Chest pain

Verzenio can cause liver problems. Tell your doctor right away if you have any of the following signs or symptoms of liver problems:

- Feeling very tired
 Loss of appetite
- Pain on the upper right side of your stomach area (abdomen)
 Bleeding or bruising more easily than normal

Verzenio may cause blood clots in your veins or lungs. These may be serious and have led to death. Tell your doctor if you have the following signs and symptoms of a blood clot:

- Pain or swelling in your arms or legs
 Chest pain
 Fast heart rate
- Shortness of breath
 Fast breathing

Please see Purpose and Safety Summary continued on page 18.



PURPOSE AND SAFETY SUMMARY (continued)

Verzenio can harm your unborn baby. Use effective birth control during treatment and for at least 3 weeks after the last dose of Verzenio and do not breastfeed during treatment with Verzenio and for at least 3 weeks after your last dose. Verzenio may affect the ability of males to father a child.

Common Side Effects

The most common side effects of Verzenio include:

- Nausea
- Infections

- Abdominal pain
- Low red blood cell counts (anemia)
- Decreased appetite
- Headache
- Hair thinning or hair loss (alopecia)
- Low white blood cell counts (leukopenia)
- Vomiting

Tiredness

Low platelet counts (thrombocytopenia)

These are not all the possible side effects of Verzenio.

Tell your doctor if you have any side effects. You can report side effects at 1-800-FDA-1088 or www.fda.gov/medwatch.

Before using

Before you use Verzenio, tell your doctor:

- If you have fever, chills, or other signs of infection
- Have liver or kidney problems
- About all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your doctor if you take a medicine that contains ketoconazole. Avoid grapefruit products while taking Verzenio. Grapefruit may increase the amount of Verzenio in your blood

How to take

- Use Verzenio exactly as your doctor tells you
- Take your doses of Verzenio at about the same time every day
- If you vomit or miss a dose take your next dose at your regular time. Do not take 2 doses of Verzenio at the same time to make up for the missed dose
- If you take too much Verzenio, call your doctor or go to the nearest hospital emergency room right away

Learn more

For more information, call 1-800-545-5979 or go to verzenio.com.

This summary provides basic information about Verzenio but does not include all information known about this medicine. Read the information that comes with your prescription each time your prescription is filled. This information does not take the place of talking with your doctor. Be sure to talk to your doctor or other healthcare provider about Verzenio and how to take it. Your doctor is the best person to help you decide if Verzenio is right for you.

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Lilly

PP-AL-US-2125 03/2020 ©Lilly USA, LLC 2020. All rights reserved. Verzenio[®] is a registered trademark and Verzenio Continuous Care[™] is a trademark owned or licensed by Eli Lilly and Company, its subsidiaries or affiliates. Other product/company names mentioned herein are the trademarks of their respective owners.