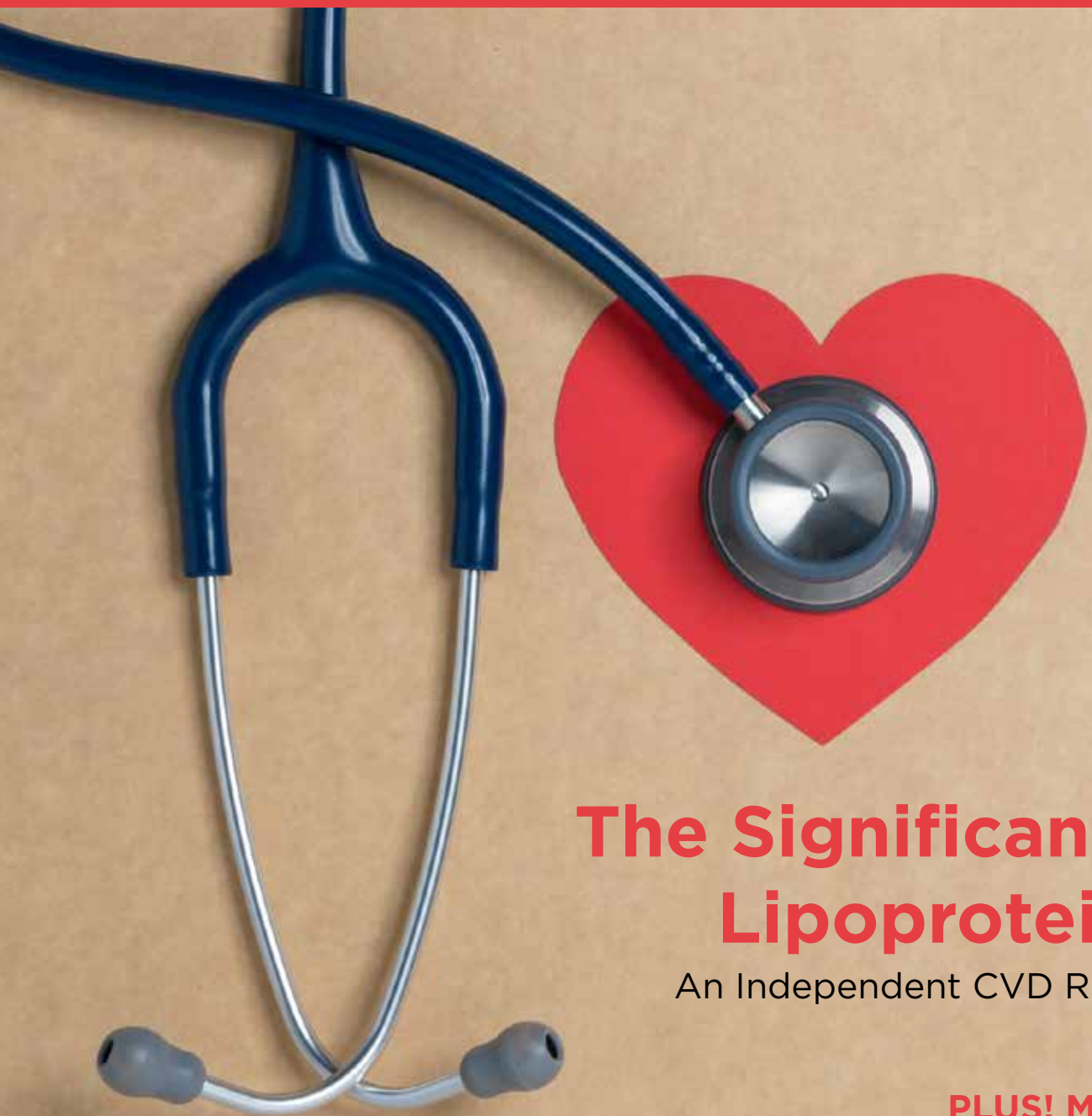
2020 | Issue 2

Physicians office Resource™

Resources for You, Your Patients, & Your Practice



The Significance of Lipoprotein(a):

An Independent CVD Risk Marker

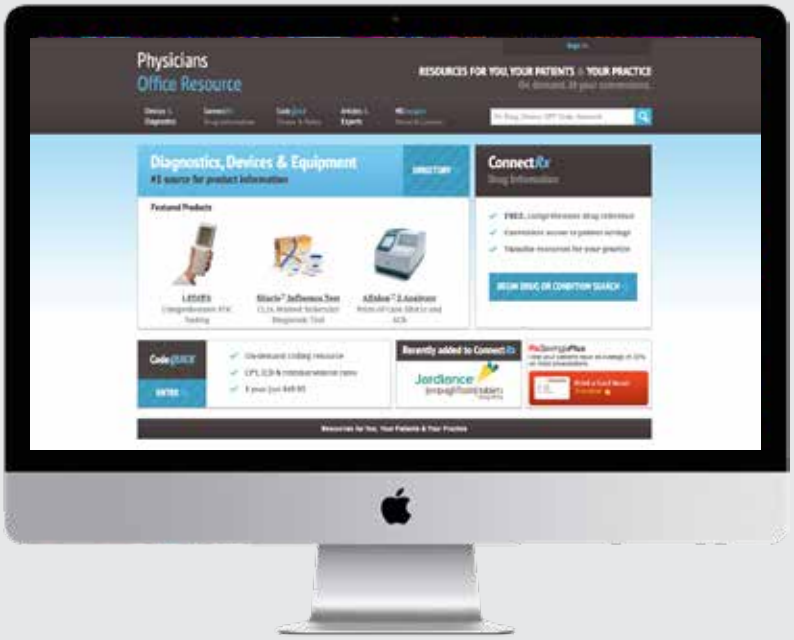
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PLUS! MDescapes

Four Seasons Resort Costa Rica

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Medical Education Resources, LLC

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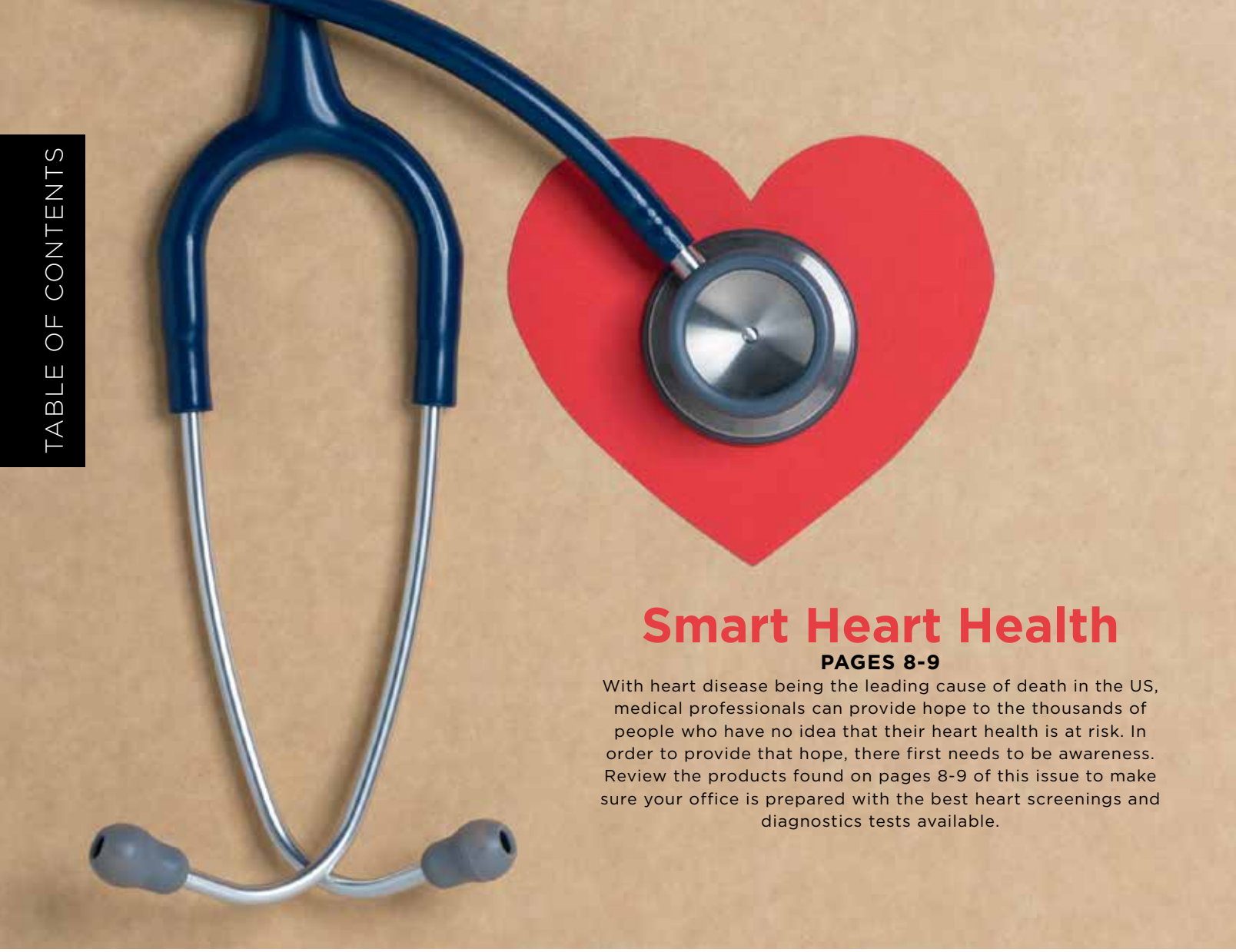
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Smart Heart Health

PAGES 8-9

With heart disease being the leading cause of death in the US, medical professionals can provide hope to the thousands of people who have no idea that their heart health is at risk. In order to provide that hope, there first needs to be awareness. Review the products found on pages 8-9 of this issue to make sure your office is prepared with the best heart screenings and diagnostics tests available.

6

Lipoprotein(a) [Lp(a)]: An Independent CVD Risk Marker

Lipoprotein(a) [Lp(a)] is described as "the most complex and polymorphic of the lipoprotein particles". Composed of a lipoprotein particle like the lipid composition similar to low-density lipoproteins (LDL) 1. The main difference between LDL and Lp(a) is that Lp(a) contains an additional protein, apolipoprotein(a) [apo(a)]. A single copy of apo(a) is covalently bonded to the apoB-100 by a single disulfide bridge (Fig 1), which differentiates Lp(a) from LDL 1, 2.

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How to Effectively Deal with Late and "No Show" Patients

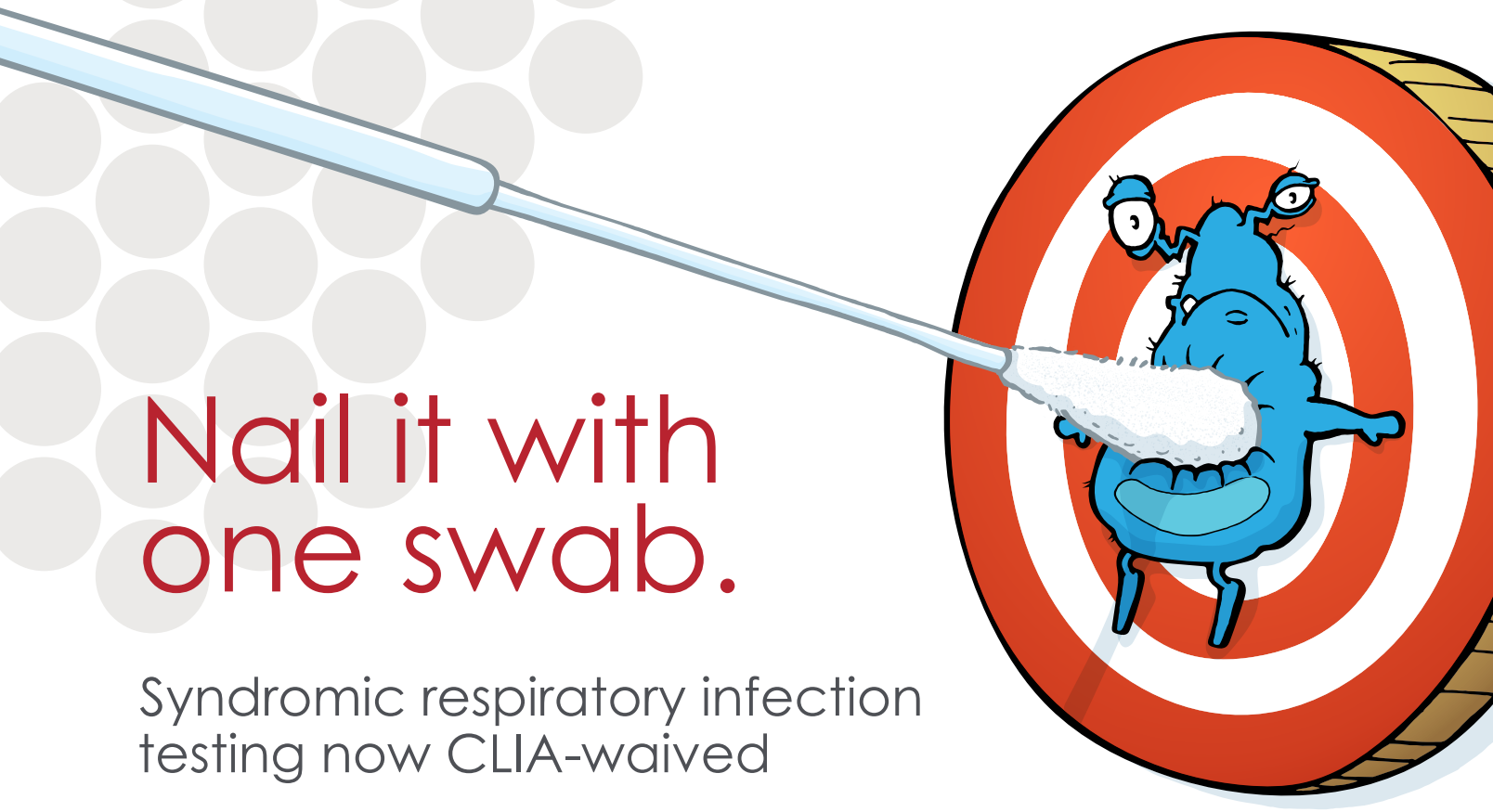
So here's the scenario: it's the middle of the week and it's late in the day. Your waiting room is full to bursting with agitated patients, bawling children and your 4:30 appointment is nowhere to be found. Phone calls, text messages and even Emails have all proven fruitless and given the outlook for the rest of the day, you're seconds away from ripping your hair out in chunks...so what do you do?



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The Pocket of Paradise that is Papagayo

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Human Metapneumovirus
Human Rhinovirus/Enterovirus
Influenza A
Influenza A/H1
Influenza A/H1-2009
Influenza A/H3
Influenza B
Parainfluenza Virus
Respiratory Syncytial Virus

Bacteria
Bordetella pertussis
Chlamydophila pneumoniae
Mycoplasma pneumoniae

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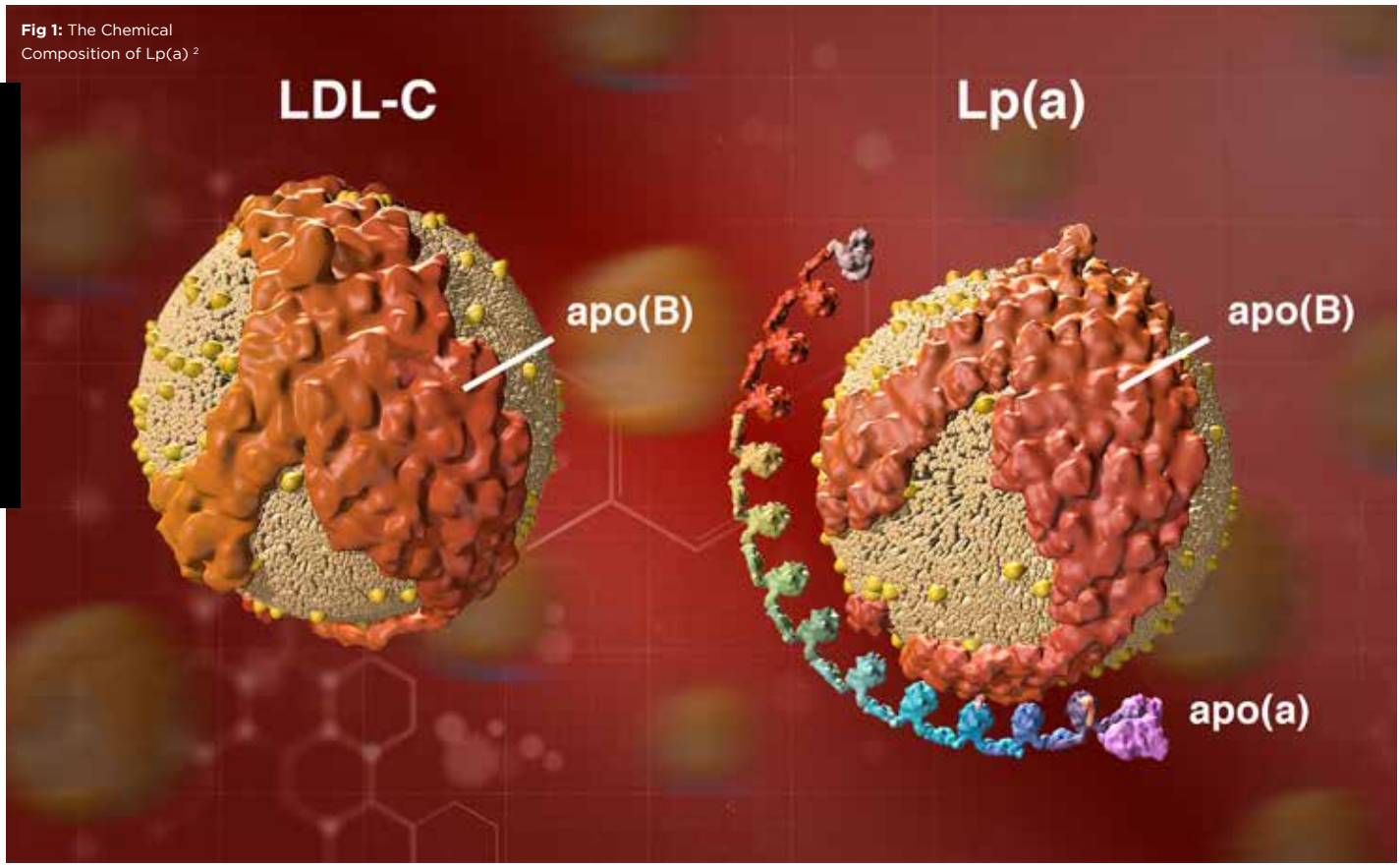


Fig 1: The Chemical Composition of Lp(a) [2]

Lipoprotein(a) [Lp(a)]:
An Independent CVD Risk Marker

BY RANDOX LABORATORIES LTD.

PHYSIOLOGICAL SIGNIFICANCE

Lp(a) Anatomy

Lipoprotein(a) [Lp(a)] is described as "the most complex and polymorphic of the lipoprotein particles". Composed of a lipoprotein particle like the lipid composition similar to low-density lipoproteins (LDL) 1. The main difference between LDL and Lp(a) is that Lp(a) contains an additional protein, apolipoprotein(a) [apo(a)]. A single copy of apo(a) is covalently bonded to the apoB-100 by a single disulfide bridge (Fig 1), which differentiates Lp(a) from LDL 1, 2.

Apo(a) Anatomy

Apo(a) is a large glycoprotein, belonging to the plasminogen gene superfamily, comprised of five cysteine-rich domains called kringles, which are coded by the LPA gene, located on the long (q) arm of chromosome 6 at positions 26 and 27 (6q26-27), and the plasminogen (PLG) gene, also located on the long (q) are of chromosome 6 at position 26 (6q26) 2, 3, 4. The PLG gene is believed to encode 5 kringles (types I to V) as well as an active protease domain. Conversely, kringles IV and V and an inactive protease domain are present in apo(a) 2. Apo(a) is described as polymorphic as the kringle type IV undergoes duplication, coding for 10 kringle IV types (K1 through K10) (Fig 2). "All kringles contain approximately 80 amino acids and are stabilized by three intrachain disulphide bonds, giving them a characteristic triple look structure". All kringles, except for KIV-2, are present as single copies. KIV-2 is present in multiple copies, ranging from 2 to >40, within the apo(a) proteins of distinct sizes. The number of KIV-2 repeats determines the size of the apo(a) isoform, thus heterogeneously affecting the size of the apo(a) protein and the plasma levels of Lp(a). An inverse correlation between the size of the apo(a) isoform and plasma concentrations of Lp(a) has been identified 2.

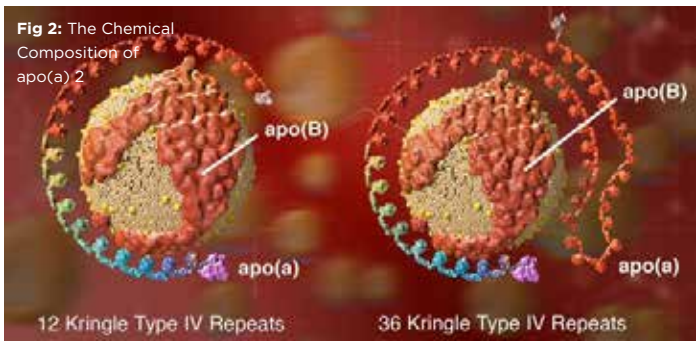


Fig 2: The Chemical Composition of apo(a) 2

CURRENT CHALLENGES IN LP(A) MEASUREMENT

The biggest challenge that exists surrounding Lp(a) measurement is

the heterogeneity of the apo(a) isoforms, resulting in the underestimation or overestimation of Lp(a) concentrations. In immunoassays, the variable numbers of repeated KIV-2 units in Lp(a) act as multiple epitopes. This is where standardisation across calibrators is vital. Unless the calibrants have the same range of isoforms as test samples, those with higher numbers of the KIV-2 repeat, will represent with an overestimation in Lp(a) concentrations and those with smaller numbers of the KIV-2 repeat, will represent with an underestimation. The smaller isoforms are strongly associated with higher Lp(a) concentrations. Lack of standardisation of the calibrant would result in an underestimation of Lp(a) associated CVD risk. It is important to note that an Lp(a) immunoassay employing isoform insensitive antibodies does not exist 5.

The gold standard Lp(a) method is the Northwest Lipid Metabolism and Diabetes Research Laboratory (NLMDRKL) method which employs an isoform insensitive antibody and is meticulously calibrated with well characterised material, however, this test is not commercially available 5.

Lp(a) assays that are standardised to the WHO/IFCC reference material (IFCC SRM 2B), transferring values from mg/dl to nmol/l are more uniformed. The Denka Seiken Lp(a) assay is the most reliable commercially available Lp(a) assay, because[5]:

1. The isoform size variations are reduced as a range of calibrators from separate pools of serum were used which covered a range of Lp(a) concentrations.

2. The isoform size and concentrations are inversely correlated better matching calibrants with test samples.

3. Methods based on the Denka Lp(a) assay, calibrated in nmol/l and traceable to the WHO/IFCC reference material gave acceptable bias compared with the NLMDRL gold standard method.

CLINICAL SIGNIFICANCE

Lp(a) measurement could be of value in those with a family history of premature CVD (<60 years), especially when a causative mutation for familial hypercholesterolemia (FH) hasn't been identified. In patients with heterozygous FH (HeFH), Lp(a) levels are higher compared to their non-affected siblings. Lp(a) has been identified as a strong risk factor of coronary heart disease (CHD) in patients with HeFH, independent of age, sex, smoking status, and LDL-C levels 5.

Lp(a) has been identified as a potent risk factor for calcific aortic valve stenosis. Understanding a patients Lp(a) levels could aid in informing the selection of the interval for valve surveillance as patients with elevated Lp(a) levels are likely to require earlier intervention 5.

Lp(a) measurements aids in the re-classifying of those deemed at an intermediate CVD risk. Patients who over 10 years have >15% risk of a CV event should be receiving treatment, such as statin therapy irrespective of Lp(a) levels 5.

RANDOX LP(A) TESTING

Randox are one of the only in vitro diagnostic manufacturers on the market to utilize the Denka Seiken method in the development of the Lp(a) assay, the most reliable commercially available assay on the market and therefore suffers minimal size related bias, providing more accurate and consistent results. Furthermore, Randox are the only in vitro diagnostics manufacturer on the market to develop an Lp(a) dedicated five-point calibrator with accuracy-based assigned target values in nmol/l and standardized to the WHO/IFCC reference material (IFCC SRM 2B) and so is the closest in terms of agreement to the NLMDRL reference method and so accurately reflects the heterogeneity of the apo(a) isoforms present in the general population. The immunoturbidimetric 'Denka' method is highly sensitive and specific for the detection of Lp(a) in serum and plasma and offers an excellent correlation coefficient of r=0.995 when compared against other commercially available methods. With an excellent within run precision of <2.54% and a liquid ready-to-use format, Randox offer a dedicated Lp(a) control offering a complete testing package. Applications are available detailing instrument-specific settings for the convenient use of the Randox Lp(a) assay on a variety of clinical chemistry analyzers. For more information, visit: www.randox.com/lipoproteina or email reagents@randox.com.

RANDOX RX DAYTONA+ & IMOLA CLINICAL CHEMISTRY ANALYZERS

Fig 3: The RX daytona+

Renowned for quality and reliability, the RX daytona+ (fig 3) and imola (fig 4) comprises the RX series extensive dedicated test menu covering a wide range of high-quality diagnostic reagents including routine chemistries, specific proteins, lipids, therapeutic drugs, antioxidants, diabetes and veterinary testing capabilities.
Placing precision, accuracy and reliability at the forefront, the RX daytona+ and imola comprise a wide range of high performance and novel assays including Lp(a), sdLDL-C, Bilirubin, Copper and NGSP certified Direct HbA1c.

The RX daytona+ and RX imola guarantee laboratories real cost savings through consolidation of routine and specialized tests onto on single platform with unrivalled uptime and performance. For more information please contact therxseries@randox.com.



Fig 3: The RX daytona+

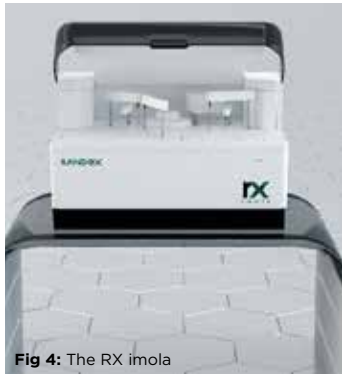


Fig 4: The RX imola

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[1] (BD Veritor System for Rapid Detection of Flu A+B, CLIA-waved kit package insert, 8087667 (14) 2018-06. BD Veritor System for Rapid Detection of Flu A+B, laboratory kit package insert, 8087666 (11) 2017-10., 2018-06.)

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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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Randox unveils new coronavirus test at Medlab Middle East 2020

A ground-breaking test for the potentially fatal 2019-nCoV strain of coronavirus, is in the final stages of development at global health diagnostics company Randox Laboratories.

The soon-to-be-launched test, developed on Randox's patented Biochip Technology, will be available for immediate 2019-nCoV testing, but an additional enhanced multiplex array will also include tests for other respiratory viruses which can display the same symptoms.

The new enhanced Biochip will therefore allow clinicians to quickly and efficiently differentiate between potentially lethal and non-lethal infections.

Dr Peter FitzGerald, Managing Director of Randox Laboratories, commented;

"Current technologies for the diagnosis of coronavirus are designed simply to detect the presence or lack of 2019-nCoV, and therefore neglect to differentiate between this strain and other respiratory infections.

"Whilst we're very quickly developing an efficient novel test for this new strain of coronavirus, we are therefore also working on an extended Viral Respiratory Infection Array that will test simultaneously for 2019-nCoV and a range of other viruses. This will eliminate the need for multiple back-and-forth tests before the root cause of symptoms is found, and empower clinicians to make fast and informed decisions."

The test will be available for the Point of Care analyser, the Vivalytic, within 3 hours, and within 5 hours on the Randox Evidence Investigator.

BENEFITS OF THE NEW RANDOX 2019-NCOV TEST

- Quick Turnaround Times (3 hours on Vivalytic and 5 hours on Evidence Investigator)
- Multiplex array differentiates between mild and serious infection
- Automated and Semi-Automated options available



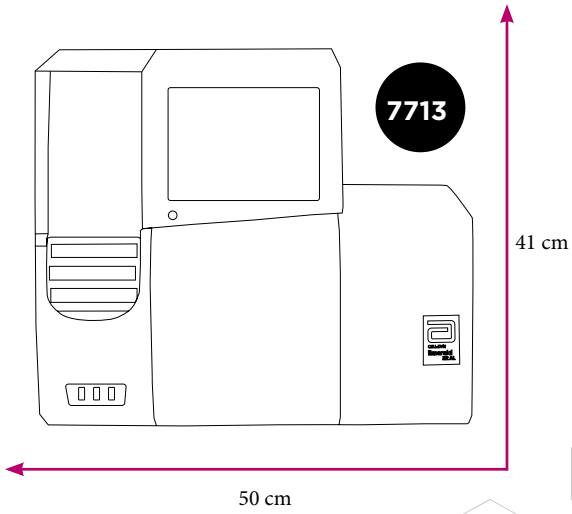
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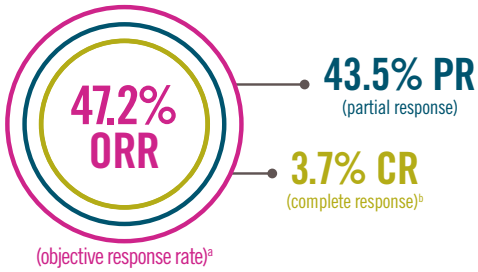
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A breakthrough for patients with advanced CSCC[1]

LIBTAYO®, a programmed death receptor-1 (PD-1) inhibitor, is the first and only FDA-approved therapy indicated for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation[1]



ORR: 51 of 108 patients; 95% confidence interval, 37.5%, 57.1%.[1,2]

61% of responders (31 of 51) reached a duration of response (DoR) of ≥6 months[1,2,a,c]

Median DoR not reached (range: 1-15.2+ months)[1-3,a,c]

[a] At time of data cutoff; based on a combined analysis of Studies 1423 and 1540, which were single-arm, open-label, multicenter, nonrandomized, multicohort studies. Median duration of follow-up was 8.9 months.[1] See additional study design details below.

[b] Only includes patients with complete healing of prior cutaneous involvement; locally advanced CSCC patients in Study 1540 required biopsy to confirm CR.[1]

[c] Group 2 patients (locally advanced CSCC; cemiplimab-rwlc 3 mg/kg every 2 weeks) who started treatment less than 9 months prior to the data cutoff date and all Group 3 patients (metastatic CSCC; cemiplimab-rwlc 350 mg every 3 weeks) from Study 1540 are excluded from the efficacy analysis set.[2]

- **Study 1423** was an open-label, multicenter, nonrandomized, multicohort study that included a total of 26 patients with metastatic CSCC or locally advanced CSCC who were not candidates for curative surgery or curative radiation. Patients received LIBTAYO 3 mg/kg intravenously every 2 weeks for up to 48 weeks. Treatment continued until progression of disease, unacceptable toxicity, or completion of planned treatment.[1]
- **Study 1540**—EMPOWER-CSCC 1—was a global, pivotal, open-label, nonrandomized, multicohort study that included a total of 137 patients with metastatic CSCC or locally advanced CSCC who were not candidates for curative surgery or curative radiation.[1,2,4] Patients received LIBTAYO 3 mg/kg intravenously every 2 weeks for up to 96 weeks or 350 mg LIBTAYO every 3 weeks for up to 54 weeks.[1,3] Treatment continued until progression of disease, unacceptable toxicity, or completion of planned treatment.[1]
- The major efficacy outcome measures were confirmed ORR, as assessed by independent central review (ICR), and ICR-assessed DoR.[1]
- Studies 1423 and 1540 excluded patients with autoimmune disease that required systemic therapy with immunosuppressant agents within 5 years; a history of solid organ transplant; prior treatment with PD-1/programmed death ligand 1 (PD-L1) blocking antibodies or other immune checkpoint inhibitor therapy; infection with HIV, hepatitis B, or hepatitis C; or Eastern Cooperative Oncology Group Performance Status ≥2.[1]
- The recommended dose of LIBTAYO is 350 mg administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity.[1]

Important Safety Information

Warnings and Precautions

Severe and Fatal Immune-Mediated Adverse Reactions

Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue and usually occur during treatment; however, they can also occur after discontinuation. Early identification and management are essential to ensuring safe use of PD-1–blocking antibodies. Monitor for symptoms and signs of immune-mediated adverse reactions. Evaluate clinical chemistries, including liver tests and thyroid function tests, at baseline and periodically during treatment. Institute medical management promptly to include specialty consultation as appropriate.

In general, withhold LIBTAYO for Grade 3 or 4 and certain Grade 2 immune-mediated adverse reactions. Permanently discontinue LIBTAYO for Grade 4 and certain Grade 3 immune-mediated adverse reactions. For Grade 3 or 4 and certain Grade 2 immune-mediated adverse reactions, administer corticosteroids (1 to 2 mg/kg/day prednisone or equivalent) or other appropriate therapy until improvement to Grade 1 or less followed by a corticosteroid taper over 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reaction is not controlled with corticosteroids. Institute hormone replacement therapy for endocrinopathies as warranted.

Immune-mediated pneumonitis: Immune-mediated pneumonitis occurred in 2.4% of 534 patients receiving LIBTAYO, including Grade 5 (0.2%), Grade 3 (0.7%), and Grade 2 (1.3%). Pneumonitis led to permanent discontinuation of LIBTAYO in 1.3% of patients. Systemic corticosteroids were required in all patients with pneumonitis, including 85% who received prednisone ≥40 mg/day or equivalent. Pneumonitis resolved in 62% of patients. Withhold LIBTAYO for Grade 2, and permanently discontinue for Grade 3 or 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

Immune-mediated colitis: Immune-mediated colitis occurred in 0.9% of 534 patients receiving LIBTAYO, including Grade 3 (0.4%) and Grade 2 (0.6%). Colitis led to permanent discontinuation of LIBTAYO in 0.2% of patients. Systemic corticosteroids were required in all patients with colitis, including 60% who received prednisone ≥40 mg/day or equivalent. Colitis resolved in 80% of patients. Withhold LIBTAYO for Grade 2 or 3, and permanently discontinue for Grade 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

Immune-mediated hepatitis: Immune-mediated hepatitis occurred in 2.1% of 534 patients receiving LIBTAYO, including Grade 5 (0.2%), Grade 4 (0.2%), and Grade 3 (1.7%). Hepatitis led to permanent discontinuation of LIBTAYO in 0.9% of patients. Systemic corticosteroids were required in all patients with hepatitis, including 91% who received prednisone ≥40 mg/day or equivalent. Hepatitis resolved in 64% of patients. Withhold LIBTAYO if AST or ALT increases to more than 3 and up to 10 times the upper limit of normal (ULN) or if total bilirubin increases up to 3 times the ULN. Permanently discontinue LIBTAYO if AST or ALT increases to more than 10 times the ULN or total bilirubin increases to more than 3 times the ULN. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

Immune-mediated endocrinopathies: Withhold LIBTAYO if clinically necessary for Grade 2, 3, or 4.

- **Adrenal insufficiency:** Adrenal insufficiency occurred in 0.4% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (0.2%)
- **Hypophysitis:** Hypophysitis, which can result in hypopituitarism, occurred in 0.2% of 534 patients receiving LIBTAYO, which consisted of 1 patient with Grade 3 hypophysitis
- **Hypothyroidism:** Hypothyroidism occurred in 6% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (5.6%); no patients discontinued hormone replacement therapy

Please see additional Important Safety Information and Brief Summary of full Prescribing Information on the following pages.

LIBTAYO demonstrated meaningful tumor reduction in clinical trial patients[1,2]

Partial responses*

These are examples from the 47.2% of patients (43.5% PR,† 3.7% CR‡) who had an objective response (defined as PRs + CRs) in clinical trials. Individual patient responses may vary.

Locally advanced CSCC Not a candidate for curative surgery or curative radiation

History
- 70-year-old male
- Auricular lesions§

Outcomes
- Best overall response: PR per WHO Criteria by independent central review
- Best percent change in target lesion(s): –91.9

Screening | **After 8 weeks** | **After 32 weeks**



Metastatic CSCC

History
- 66-year-old male
- Clavicular lesions

Outcomes
- Best overall response: PR per RECIST 1.1 by independent central review
- Best percent change in target lesion(s): –71.1

Screening | **After 8 weeks** | **After 48 weeks**



*Results as of data cutoff. Group 2 patients (laCSCC; cemiplimab-rwlc 3 mg/kg Q2W) who started treatment less than 9 months prior to the data cutoff date and all Group 3 patients (mCSCC; cemiplimab-rwlc 350 mg Q3W) from Study 1540 are excluded from the efficacy analysis set.[2]

† Partial response is defined as a decrease of 30% or greater in the sum of the diameters of target lesions, taking as reference the baseline sum of diameters, per RECIST 1.1. Partial response of externally visible disease is defined as a decrease of 50% or greater in the sum of products of perpendicular longest dimensions of target lesions, per WHO Criteria. Responses had to be maintained for at least 4 weeks.[2]

‡ Complete response is defined as disappearance of all target lesions for at least 4 weeks. Only includes patients with complete healing of prior cutaneous involvement; locally advanced CSCC patients in Study 1540 required biopsy to confirm CR.[1,2]

§ This patient also had cranial lesions that were included in the calculation of best percent change in target lesion(s). Those images are not included here.[2]

laCSCC, locally advanced cutaneous squamous cell carcinoma; mCSCC, metastatic cutaneous squamous cell carcinoma; Q2W, every 2 weeks; Q3W, every 3 weeks; RECIST, Response Evaluation Criteria in Solid Tumors; WHO, World Health Organization.

See more patient profiles at LIBTAYOhcp.com.

Important Safety Information

Warnings and Precautions

Severe and Fatal Immune-Mediated Adverse Reactions

Immune-mediated endocrinopathies (continued):

- **Hyperthyroidism:** Hyperthyroidism occurred in 1.5% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (0.4%); hyperthyroidism resolved in 38% of patients
- **Type 1 diabetes mellitus:** Type 1 diabetes mellitus, which can present with diabetic ketoacidosis, occurred in 0.7% of 534 patients, including Grade 4 (0.4%) and Grade 3 (0.4%); type 1 diabetes mellitus led to permanent discontinuation of LIBTAYO in 0.2% of patients

Immune-mediated nephritis with renal dysfunction: Immune-mediated nephritis occurred in 0.6% of 534 patients receiving LIBTAYO, including Grade 3 (0.4%) and Grade 2 (0.2%). Nephritis led to permanent discontinuation of LIBTAYO in 0.2% of patients. Systemic corticosteroids were required in all patients with nephritis, including 67% who received prednisone ≥40 mg/day or equivalent. Nephritis resolved in all patients. Withhold LIBTAYO for Grade 3, and permanently discontinue for Grade 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

Immune-mediated dermatologic adverse reactions: Immune-mediated dermatologic reactions, including erythema multiforme and pemphigoid, occurred in 1.7% of 534 patients receiving LIBTAYO, including Grade 3 (1.1%) and Grade 2 (0.6%). In addition, SJS and TEN have been observed with LIBTAYO and with other products in this class. Systemic corticosteroids were required in all patients with dermatologic reactions, including 89% who received prednisone ≥40 mg/day or equivalent. Dermatologic reactions resolved in 33% of patients. Approximately 22% of patients had recurrence of dermatologic reactions after re-initiation of LIBTAYO. Withhold LIBTAYO for Grade 3, and permanently discontinue for Grade 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

Other immune-mediated adverse reactions: The following clinically significant immune-mediated adverse reactions occurred at an incidence of <1% in 534 patients who received LIBTAYO or were reported with the use of other PD-1–blocking and PD-L1–blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions. Withhold LIBTAYO for Grade 3, and permanently discontinue for Grade 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

- **Neurological:** Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis, Guillain-Barré syndrome, nerve paresis, and autoimmune neuropathy
- **Cardiovascular:** Myocarditis, pericarditis, and vasculitides
- **Ocular:** Uveitis, iritis, and other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various Grades of visual impairment to include blindness can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada–like syndrome, as this may require treatment with systemic corticosteroids to reduce the risk of permanent vision loss
- **Gastrointestinal:** Pancreatitis to include increases in serum amylase and lipase levels, gastritis, and duodenitis
- **Musculoskeletal and connective tissue:** Myositis, rhabdomyolysis, and associated sequelae, including renal failure, arthritis, and polymyalgia rheumatica
- **Hematological and immunological:** Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, and solid organ transplant rejection

Infusion-related reactions

Severe infusion-related reactions (Grade 3) occurred in 0.2% of patients receiving LIBTAYO. Monitor patients for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of infusion for Grade 1 or 2, and permanently discontinue for Grade 3 or 4.

Embryo-fetal toxicity

LIBTAYO can cause fetal harm when administered to a pregnant woman due to an increased risk of immune-mediated rejection of the developing fetus resulting in fetal death. Advise women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with LIBTAYO and for at least 4 months after the last dose.

Adverse reactions

- Serious adverse reactions occurred in 28% of patients. Serious adverse reactions that occurred in ≥2% of patients were cellulitis, sepsis, pneumonia, pneumonitis, and urinary tract infection. The most common Grade 3-4 adverse reactions (≥2%) were cellulitis, sepsis, hypertension, pneumonia, musculoskeletal pain, skin infection, urinary tract infection, and fatigue
- LIBTAYO was permanently discontinued due to adverse reactions in 5% of patients; adverse reactions resulting in permanent discontinuation were pneumonitis, autoimmune myocarditis, hepatitis, aseptic meningitis, complex regional pain syndrome, cough, and muscular weakness
- The most common adverse reactions (incidence ≥20%) were fatigue, rash, and diarrhea

Use in specific populations

- **Lactation:** Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for at least 4 months after the last dose of LIBTAYO
- **Females and males of reproductive potential:** Verify pregnancy status in females of reproductive potential prior to initiating LIBTAYO

Please see Brief Summary of full Prescribing Information on the following page.

References: 1. LIBTAYO (cemiplimab-rwlc) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc., and sanofi-aventis U.S. LLC. **2.** Data on file. Regeneron Pharmaceuticals Inc. **3.** Migden MR et al. *N Engl J Med.* 2018;379(4):341-351. **4.** Study of REGN2810 in patients with advanced cutaneous squamous cell carcinoma. Clinicaltrials.gov. https://clinicaltrials.gov/ct2/show/study/NCT02760498. Published May 3, 2016. Updated January 14, 2019. Accessed June 10, 2019.

To learn more about LIBTAYO, speak with your sales representative or visit LIBTAYOhcp.com.

REGENERON | SANOFI GENZYME

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LIBTAYO®
(cemiplimab-rwlc)
Injection 350 mg

LIBTAYO® (cemiplimab-rwlc) injection, for intravenous use

Brief Summary of Prescribing Information

1 INDICATIONS AND USAGE

LIBTAYO is indicated for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Severe and Fatal Immune-Mediated Adverse Reactions

LIBTAYO is a monoclonal antibody that belongs to a class of drugs that binds to the programmed death receptor-1 (PD-1), blocking the PD-1/PD-L1 pathway, thereby removing inhibition of the immune response with the potential for breaking of peripheral tolerance and induction of immune-mediated adverse reactions. Important immune-mediated adverse reactions listed under Warnings and Precautions may not be inclusive of all possible immune-mediated reactions.

Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue. While immune-mediated adverse reactions usually manifest during treatment with PD-1/PD-L1 blocking antibodies, immune-mediated adverse reactions can also manifest after discontinuation of PD-1/PD-L1 blocking antibodies.

Early identification and management are essential to ensure safe use of PD-1/PD-L1 blocking antibodies. Monitor for symptoms and signs of immune-mediated adverse reactions. Evaluate clinical chemistries, including liver tests and thyroid function tests, at baseline and periodically during treatment. Institute medical management promptly to include specialty consultation as appropriate.

In general, withhold LIBTAYO for Grade 3 or 4 and certain Grade 2 immune-mediated adverse reactions. Permanently discontinue LIBTAYO for Grade 4 and certain Grade 3 immune-mediated adverse reactions *[see Dosage and Administration (2.2)]*. For Grade 3 or 4 and certain Grade 2 immune-mediated adverse reactions, administer corticosteroids (1 to 2 mg/kg/day prednisone or equivalent) or other appropriate therapy until improvement to Grade 1 or less followed by a corticosteroid taper over one month *[see Dosage and Administration (2.2)]*. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reaction is not controlled with corticosteroids. Institute hormone replacement therapy for endocrinopathies as warranted.

Immune-Mediated Pneumonitis

Immune-mediated pneumonitis occurred in 2.4% of 534 patients receiving LIBTAYO, including Grade 5 (0.2%), Grade 3 (0.7%) and Grade 2 (1.3%) *[see Adverse Reactions (6.1)]*. Pneumonitis led to permanent discontinuation of LIBTAYO in 1.3% of patients. Systemic corticosteroids were required in all patients with pneumonitis, including 85% who received prednisone ≥40 mg per day or equivalent. Pneumonitis resolved in 62% of patients.

Immune-Mediated Colitis

Immune-mediated colitis occurred in 0.9% of 534 patients receiving LIBTAYO, including Grade 3 (0.4%) and Grade 2 (0.6%) *[see Adverse Reactions (6.1)]*. Colitis led to permanent discontinuation of LIBTAYO in 0.2% of patients. Systemic corticosteroids were required in all patients with colitis, including 60% who received prednisone ≥40 mg per day or equivalent. Colitis resolved in 80% of patients.

Immune-Mediated Hepatitis

Immune-mediated hepatitis occurred in 2.1% of 534 patients receiving LIBTAYO, including Grade 5 (0.2%), Grade 4 (0.2%), and Grade 3 (1.7%) *[see Adverse Reactions (6.1)]*. Hepatitis led to permanent discontinuation of LIBTAYO in 0.9% of patients. Systemic corticosteroids were required in all patients with hepatitis, including 91% who received prednisone ≥40 mg per day or equivalent. Hepatitis resolved in 64% of patients.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

Adrenal insufficiency occurred in 0.4% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%), and Grade 2 (0.2%) *[see Adverse Reactions (6.1)]*.

Hypophysitis

Hypophysitis, which can result in hypopituitarism, occurred in 0.2% of 534 patients receiving LIBTAYO, which consisted of one patient with Grade 3 hypophysitis.

Hypothyroidism

Hypothyroidism occurred in 6% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (5.6%). No patients discontinued hormone replacement therapy.

Hyperthyroidism

Hyperthyroidism occurred in 1.5% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (0.4%). Hyperthyroidism resolved in 38% of patients.

Type 1 Diabetes Mellitus

Type 1 diabetes mellitus, which can present with diabetic ketoacidosis, occurred in 0.7% of 534 patients, including Grade 4 (0.4%) and Grade 3 (0.4%). Type 1 diabetes mellitus led to permanent discontinuation of LIBTAYO in 0.2% of patients.

Immune-Mediated Nephritis with Renal Dysfunction

Immune-mediated nephritis occurred in 0.6% of 534 patients receiving LIBTAYO, including Grade 3 (0.4%) and Grade 2 (0.2%) *[see Adverse Reactions (6.1)]*. Nephritis led to permanent discontinuation of LIBTAYO in 0.2% of patients. Systemic corticosteroids were required in all patients with nephritis, including 67% who received prednisone ≥40 mg per day or equivalent. Nephritis resolved in all patients.

Immune-Mediated Dermatologic Adverse Reactions

Immune-mediated dermatologic reactions, including erythema multiforme and pemphigoid, occurred in 1.7% of 534 patients receiving LIBTAYO, including Grade 3 (1.1%) and Grade 2 (0.6%) *[see Adverse Reactions (6.1)]*. In addition, SJS and TEN have been observed with LIBTAYO and with other products in this class. Systemic corticosteroids were required in all patients with dermatologic reactions, including 89% who received prednisone ≥40 mg per day or equivalent. Dermatologic reactions resolved in 33% of patients. Approximately 22% of patients had recurrence of dermatologic reactions after re-initiation of LIBTAYO.

Other Immune-Mediated Adverse Reactions

The following clinically significant immune-mediated adverse reactions occurred at an incidence of <1% in 534 patients who received LIBTAYO *[see Adverse Reactions (6.1)]* or were reported with the use of other PD-1/PD-L1 blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions.

Neurological: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome / myasthenia gravis, Guillain-Barre syndrome, nerve paresis, autoimmune neuropathy

Cardiovascular: Myocarditis, pericarditis, vasculitides

Ocular: Uveitis, iritis, and other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada like syndrome, as this may require treatment with systemic corticosteroids to reduce the risk of permanent vision loss.

Gastrointestinal: Pancreatitis to include increases in serum amylase and lipase levels, gastritis, duodenitis

Musculoskeletal and Connective Tissue: Myositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatica

Hematological and Immunological: Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection

5.2 Infusion-Related Reactions

Severe infusion-related reactions (Grade 3) occurred in 0.2% of patients receiving LIBTAYO *[see Adverse Reactions (6.1)]*. Monitor patients for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of infusion or permanently discontinue LIBTAYO based on severity of reaction *[see Dosage and Administration (2.2)]*.

5.3 Embryo-Fetal Toxicity

Based on its mechanism of action, LIBTAYO can cause fetal harm when administered to a pregnant woman. Animal studies have demonstrated that inhibition of the PD-1/PD-L1 pathway can lead to increased risk of immune-mediated rejection of the developing fetus resulting in fetal death. Advise women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with LIBTAYO and for at least 4 months after the last dose *[see Use in Specific Populations (8.1, 8.3)]*.

6 ADVERSE REACTIONS

The following serious adverse reactions are described elsewhere in the labeling.

- Severe and Fatal Immune-Mediated Adverse Reactions *[see Warnings and Precautions (5.1)]*
- Infusion-Related Reactions *[see Warnings and Precautions (5.2)]*

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 described in WARNINGS AND PRECAUTIONS reflect exposure to LIBTAYO in 534 patients in two open-label, single-arm, multicohort studies (Study 1423 and Study 1540), including 98 patients with metastatic (nodal or distant) CSCC, 65 patients with locally advanced CSCC, and 371 patients with other advanced solid tumors. LIBTAYO as a single agent or in combination with chemotherapy or radiation was administered intravenously at doses of 1 mg/kg every 2 weeks (n=27), 3 mg/kg every 2 weeks (n=446), 3 mg/kg every 3 weeks (n=12), 10 mg/kg every 2 weeks (n=6), 200 mg every 2 weeks (n=20) or 350 mg every 3 weeks (n=23). Among the 534 patients, 38% were exposed for ≥6 months and 16% were exposed for ≥12 months.

The data described below reflect exposure to LIBTAYO in 163 patients with advanced CSCC (metastatic or locally advanced disease) in Study 1423 and Study 1540. Patients received LIBTAYO 1 mg/kg every 2 weeks (n=1), 3 mg/kg every 2 weeks (n=139) or 350 mg every 3 weeks (n=23) as an intravenous infusion until disease progression, unacceptable toxicity, or completion of planned treatment. The median duration of exposure was 20 weeks (3 days to 1.4 years).

The safety population characteristics were: median age of 71 years (38 to 96 years), 85% male, 96% white, and ECOG performance score (PS) of 0 (44%) or 1 (56%).

The most common adverse reactions reported in at least 20% of patients were fatigue, rash and diarrhea. The most common Grade 3-4 adverse reactions (≥2%) were cellulitis, sepsis, hypertension, pneumonia, musculoskeletal pain, skin infection, urinary tract infection and fatigue. LIBTAYO was permanently discontinued due to adverse reactions in 5% of patients; adverse reactions resulting in permanent discontinuation were pneumonitis, autoimmune myocarditis, hepatitis, aseptic meningitis, complex regional pain syndrome, cough, and muscular weakness. Serious adverse reactions occurred in 28% of patients. Serious adverse reactions that occurred in at least 2% of patients were cellulitis, sepsis, pneumonia, pneumonitis and urinary tract infection.

Table 1 summarizes the adverse reactions that occurred in ≥10% of patients and Table 2 summarizes Grade 3 and 4 laboratory abnormalities worsening from baseline in ≥1% of patients receiving LIBTAYO.

Table 1: Adverse Reactions in ≥10% of Patients with Advanced CSCC Receiving LIBTAYO in Study 1423 and Study 1540

Adverse Reactions	LIBTAYO N=163	
	All Grades %	Grade 3-4 %
Skin and Subcutaneous Tissue		
Rash*	25	1.2
Pruritus†	15	0
Gastrointestinal		
Diarrhea‡	22	0.6
Nausea	19	0
Constipation	12	0.6
General and Administration Site		
Fatigue§	29	2
Musculoskeletal and Connective Tissue		
Musculoskeletal pain#	17	3
Metabolism and Nutrition		
Decreased appetite	10	0

* Rash is a composite term that includes rash maculopapular, rash, dermatitis, rash generalized, dermatitis bullous, drug eruption, erythema, rash erythematous, rash macular, rash pruritic, and skin reaction.
† Pruritus is a composite term that includes pruritus and pruritus allergic.
‡ Diarrhea is a composite term that includes diarrhea and colitis.
§ Fatigue is a composite term that includes fatigue and asthenia.
# Musculoskeletal pain is a composite term that includes: musculoskeletal pain, back pain, myalgia, neck pain, pain in extremity.

Table 2: Grade 3 or 4 Laboratory Abnormalities Worsening from Baseline in ≥1% of Patients with Advanced CSCC Receiving LIBTAYO in Study 1423 and Study 1540

Laboratory Abnormality	Grade 3-4 (%)†
Chemistry	
Increased aspartate aminotransferase	3
Increased INR	2
Hypoalbuminemia	1
Hematology	
Lymphopenia	7
Anemia	2
Electrolytes	
Hypophosphatemia	4
Hyponatremia	3
Hypercalcemia	1

† Percentages are based on the number of patients with at least 1 post-baseline value available for that parameter.

6.2 Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to cemiplimab-rwlc in the studies described below with the incidence of antibodies in other studies or to other products may be misleading.

Anti-drug antibodies (ADA) were tested in 398 of 534 patients who received LIBTAYO and the incidence of cemiplimab-rwlc treatment-emergent ADAs was 1.3% using an electrochemiluminescent (ECL) bridging immunoassay; 0.3% were persistent ADA responses. In the patients who developed anti-cemiplimab-rwlc antibodies, there was no evidence of an altered pharmacokinetic profile of cemiplimab-rwlc.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Based on its mechanism of action, LIBTAYO can cause fetal harm when administered to a pregnant woman. There are no available data on the use of LIBTAYO in pregnant women. Animal studies have demonstrated that inhibition of the PD-1/PD-L1 pathway can lead to increased risk of immune-mediated rejection of the developing fetus resulting in fetal death *(see Data)*. Human IgG4 immunoglobulins (IgG4) are known to cross the placenta; therefore, LIBTAYO has the potential to be transmitted from the mother to the developing fetus. Advise women of the potential risk to a fetus.

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

Animal reproduction studies have not been conducted with LIBTAYO to evaluate its effect on reproduction and fetal development. A central function of the PD-1/PD-L1 pathway is to preserve pregnancy by maintaining maternal immune tolerance to the fetus. In murine models of pregnancy, blockade of PD-L1 signaling has been shown to disrupt tolerance to the fetus and to result in an increase in fetal loss; therefore, potential risks of administering LIBTAYO during pregnancy include increased rates of abortion or stillbirth. As reported in the literature, there were no malformations related to the blockade of PD-1/PD-L1 signaling in the offspring of these animals; however, immune-mediated disorders occurred in PD-1 and PD-L1 knockout mice. Based on its mechanism of action, fetal exposure to cemiplimab-rwlc may increase the risk of developing immune-mediated disorders or altering the normal immune response.

8.2 Lactation

Risk Summary

There is no information regarding the presence of cemiplimab-rwlc in human milk, or its effects on the breastfed child or on milk production. Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for at least 4 months after the last dose of LIBTAYO.

8.3 Females and Males of Reproductive Potential

Pregnancy Testing

Verify pregnancy status in females of reproductive potential prior to initiating LIBTAYO *[see Use in Specific Populations (8.1)]*.

Contraception

LIBTAYO can cause fetal harm when administered to a pregnant woman *[see Use in Specific Populations (8.1)]*.

Females

Advise females of reproductive potential to use effective contraception during treatment with LIBTAYO and for at least 4 months after the last dose.

8.4 Pediatric Use

The safety and effectiveness of LIBTAYO have not been established in pediatric patients.

8.5 Geriatric Use

Of the 163 patients with metastatic and locally advanced CSCC who received LIBTAYO in clinical studies, 72% were 65 years or older and 37% were 75 years or older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects.

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US-LIB-1510 04/19

4 WAYS TO START IMMEDIATELY INCREASING REVENUE



1 ANS TESTING (can be combined with SUDOMOTOR into 1 full system)

- Takes less than 10 minutes to perform, software provides verbal cues
- Tests for autonomic balance, vascular health, physical/mental stress, peripheral nerve health and other critical hidden risk factors
- Reimburses $170/test using 3 CPT codes
- Provides a 1 page summary up to a full 24 page comprehensive report

7714



2 SUDOMOTOR TESTING (can be combined with ANS into 1 full system)

- Takes 3 minutes to analyze a patients' hands and feet
- Provides a 1 page summary report
- Assesses peripheral nerve health (c-fiber function) and asymmetry between each hand and foot
- Reimburses $130/test (national average)

7715



3 ALLERGY TESTING

- Turn Key, comprehensive system
- 80-panel test, NO HIGH RISK (shellfish/peanuts/berries)
- 2 Minutes to apply, 15 minutes to show results
- Reimburses average $270 - $350/test, costs ~ $100/test (antigens/applicators)
- Options for Immunotherapy Treatment

7716



4 NEURO-COGNITIVE TESTING

7717

- Medicare mandates yearly cognitive assessment
- Takes 10-15 minutes to prep patient, 20 minutes to test
- Analyzes: brain health (EEG), brain processing speed (Evoke Potentials), heart health (EKG), mental health (neuropsychology)
- Reimburses using 6 CPT codes, National Average = $750 - $1000 per test
- Each test is processed into a fully-finished, clinically actionable report
- Easy to understand biomarkers facilitate more informed medical interventions, such as biofeedback

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How to Effectively Deal with Late and "No Show" Patients

BY DYLAN CHADWICK

So here's the scenario: it's the middle of the week and it's late in the day. Your waiting room is full to bursting with agitated patients, bawling children and your 4:30 appointment is nowhere to be found. Phone calls, text messages and even Emails have all proven fruitless and given the outlook for the rest of the day, you're seconds away from ripping your hair out in chunks...so what do you do?

Before we explore the veritable ins and outs of patients lateness, let's touch on one obvious, but important fact: chronically late, and patients who altogether miss their scheduled appointments (referred to as "no show patients" for the remainder of this article) can throw an already tepid schedule horribly out of whack. From minor tardiness foibles, to extensive "no call, no show" episodes, here's a few things to keep in mind when dealing with these kinds of patient scenarios, and how hurried physicians can keep things on track even when the appointment book isn't.

IMMEDIATELY IDENTIFY THE SOURCE OF THE PROBLEM

Before rushing to any kind of action, whenever possible it's important for physicians to directly contact the patient to get to the bottom of the problem. Generally speaking, patients have a good reason for not showing up to a scheduled appointment on time. Maybe it's a house full of mischievous kids or delayed traffic due to a wreck on the freeway. Compound these kinds of day-to-day life struggles with the general embarrassment that they may already feel from running late, and

you run into a potential "no show" problem. When a caring physician takes time to establish honest contact with the patient, insomuch that communication can occur, often times these problems can be solved with nary a hassle. However, it's important to remember that these can be delicate subjects, so inquiring physicians should tread lightly. If a patient can tell that the physician is making contact to better serve their medical needs, and not to chide or pass judgment, they are more likely to be open and forthright, and in turn, more likely to correct the problem down the road. In her Physician's News article Dealing with Frequently Late Patients, Audrey McLaughlin, RN, suggests charting the patient's answers and making notes in the appointment system. For example, if it's known that the patient is a single parents struggling to get three kids in the road every single time she makes an appointment, these types of factors can be made when planning future appointments. Perhaps they can be strategically planned for a time the kids are at school, or they can be made earlier in the day to allow a buffer period for lateness. In all cases, communication is key.

WRITTEN WARNINGS

We're all familiar with the pink slips given in grade school to warn parents of errant child behavior. So too can a patient call attention to problematic patient behavior. Patients should remember that this isn't a "shaming" procedure, but a simple, albeit firm reminder that patients should do their absolute best to keep their appointments. These warnings shouldn't be condescending or emotional, but brief, friendly and business-like. It's also important to remember that in some cases, patients may not even know that they're late, or that their lateness is a problem. Including a simple detail such as "in order for us to adequately provide for all of our patients with scheduled appointments today, it is of utmost importance that you are on time to your appointments so as not to disrupt the schedule of anyone else."

Some physicians like to give as many warnings as possible, and so a "tiered" written warning system may be put into place. For instance, patients who commit their first "offense" (perhaps they are more than 15 minutes late for their appointment) are given a friendly written warning and an invitation to keep future appointments without lateness. A second offense will be slightly more firm, stating something like "this is the second appointment for which you have arrived late. If there's any way we can adjust your appointments to make them more appropriate, please let us know." Finally, on a third offense, more drastic action can be taken. Some physicians will "fire" a patient who is late for three appointments in a row, while others think this is too harsh. This is a decision that should be made with the help of staff and a careful consideration of everything from general patient load, to hour-by-hour busy-ness before rendering any final ruling.

OPEN THE DOOR FOR COMMUNICATION BACK

As stated earlier, late patients generally know they are late. When a physician goes out of their way to let the patient know that they can call and get in touch, it may eliminate communication snags in the future. In fact, some patients may not even be aware of the fact that they can call to give a pre-emptive warning that they're running late. It may be helpful to establish a practice policy for cancelling appointments. If a patient is made well aware of the policy, they're much more likely to follow it when it comes up.

Additionally, physicians can let patients know that "no call, no show" appointments aren't only inconvenient...but can be hazardous to their health. In the event that a legitimate or complicated health problem should arise, it is troubling for physicians when patients aren't making their appointments to receive consultation and treatment.

CREATIVE SCHEDULING

This is a procedure that should be done carefully, and only with patients with a long and chronic history of lateness, but can prevent scheduling snafus, particularly with office software and wait staff. For those patients who always seem to run 15-30 minutes later than their scheduled appointment, simply put their appointment in the system a half an hour later than the agreed upon time. For example, if the appointment is made for 3:00 PM, schedule it for 3:30 PM without telling the patient. That way, when the patient shows up predictably late for their 3:00 PM appointment, the computer is none the wiser and no real adjustments must be made. However, it should be noted that some practices may not wish to do this, as it can be seen as a) "rewarding" the "misbehavior" of the patient and b) confusing to those in charge of scheduling, particularly in cases of new hires to wait staff, who aren't as familiar with the patient base.

PENALTIES

Please note that I do use the term "penalties" quite lightly here, but they are penalties none the less. In cases where exceptions cannot be made and where late and no show patients are creating more chaos than can be controlled, small penalties can be a prime motivator. Nominal fees, such as $25-50 for unexplained missed appointments, or for a "third strike" late appointment may be what keeps patients on the clock. In some cases, a simple WARNING of the penalties that CAN occur for a late or abandoned appointment will be enough to dissuade an errant behavior. When these measures are taken, they should always be accompanied with plenty of warning, and in every case with a measure of understanding. Patients need to know that the only reason they are being penalized is because they are putting more unnecessary work on you as the physician and are also disrupting the schedules of patients who have been diligent about keeping their appointments.

CONCLUSION

Ultimately, it's important for patients to see that physicians just want to be the best caregivers they can. They aren't in the business of "shaming" others, nor are they trying to judge. Patients who can see that a practice is run with efficiency and authority are far more likely to abide by its policies, and to comply with treatment, when they can see caring physicians at the helm. To quote Rebecca Fox, MD's Physician's News article Dealing with Late and No Show Patients, "all in all, the best practice is to use compassion and empathy. Remember that even though you are in the business of medicine, you are still in the customer service business."

Of course it'd be ridiculous to posit that anything could be a cure-all for the busy physician schedule. Daily, they are prone to knock out of skew one way or the other, with very little warning. Still, when physicians and patients are both working together to keep things steady and on course, the ship sales much smoother, and with much fewer disruptions.

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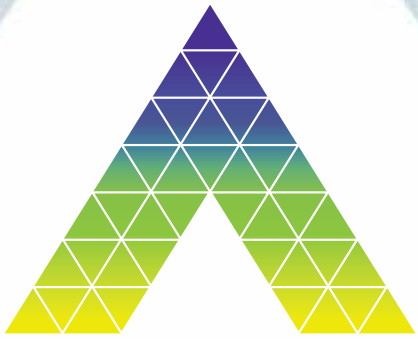


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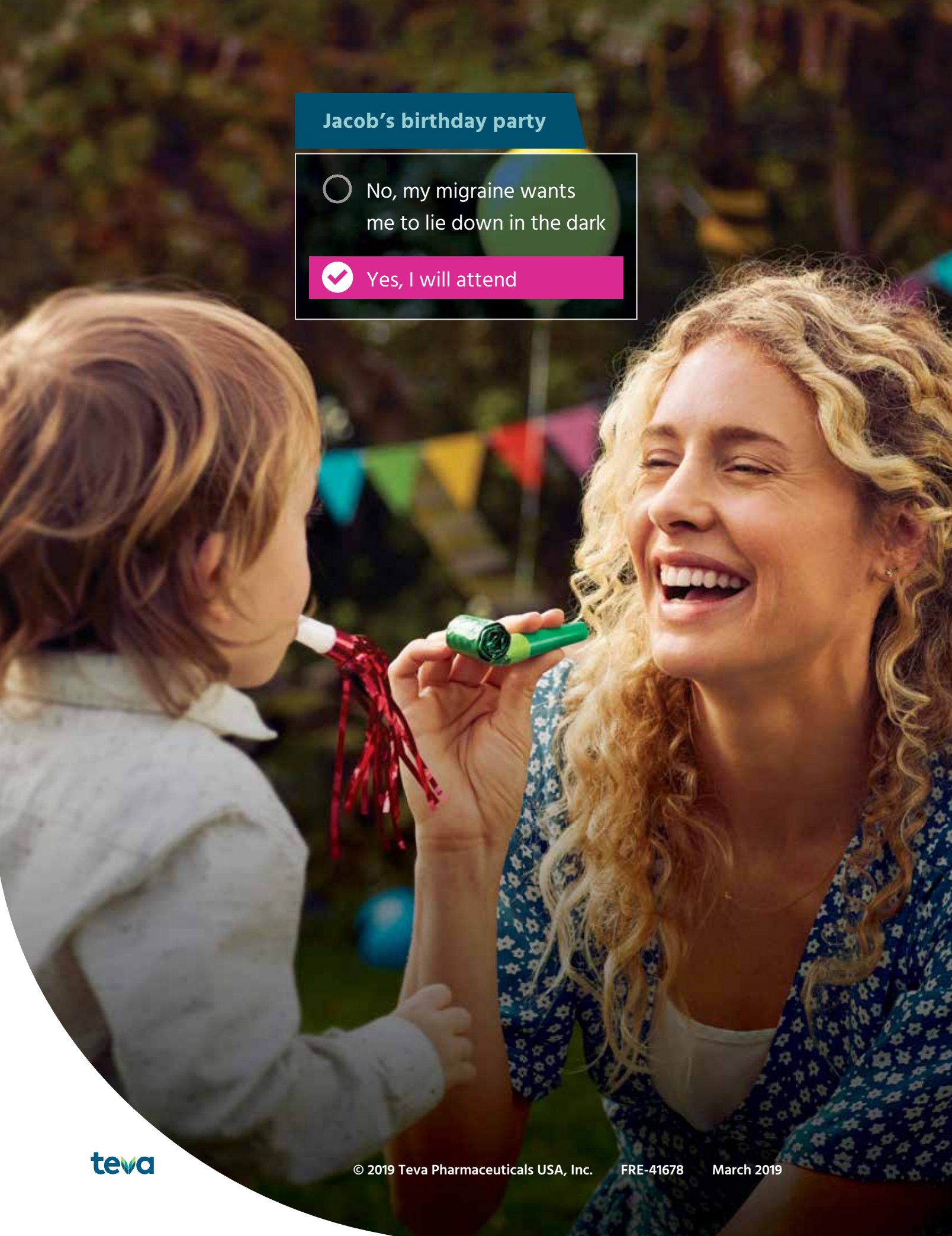
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†RSV- Respiratory Syncytial Virus

References:
1. BD Veritor System for Rapid Detection of Flu A+B, CLIA-waived kit package insert, 8087667 (14) 2018-06.
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Less migraine. More moments.™

Help patients say yes to more moments

- **AJOVY® (fremanezumab-vfrm) injection is the only anti-CGRP treatment for the prevention of migraine with quarterly and monthly dosing options[1]**
- **More migraine-free days with AJOVY in clinical trials[1]**

INDICATION

AJOVY is indicated for the preventive treatment of migraine in adults.

IMPORTANT SAFETY INFORMATION

Contraindications: AJOVY is contraindicated in patients with serious hypersensitivity to fremanezumab-vfrm or to any of the excipients.

Hypersensitivity Reactions: Hypersensitivity reactions, including rash, pruritus, drug hypersensitivity, and urticaria were reported with AJOVY in clinical trials. Most reactions were mild to moderate, but some led to discontinuation or required corticosteroid treatment. Most reactions were reported from within hours to one month after administration. If a hypersensitivity reaction occurs, consider discontinuing AJOVY and institute appropriate therapy.

Adverse Reactions: The most common adverse reactions (≥5% and greater than placebo) were injection site reactions.

Please see Brief Summary of full Prescribing Information on the following page.

To learn more, visit AJOVYhcp.com

CGRP: calcitonin gene-related peptide.

Reference: 1. AJOVY® (fremanezumab-vfrm) injection Current Prescribing Information. North Wales, PA: Teva Pharmaceuticals USA, Inc.

AJOVY®
(fremanezumab-vfrm)
injection 225 mg/1.5 mL

BRIEF SUMMARY OF PRESCRIBING INFORMATION FOR
AJOVY® (fremanezumab-vfrm) injection, for subcutaneous use
SEE PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

AJOVY is indicated for the preventive treatment of migraine in adults.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage

Two subcutaneous dosing options of AJOVY are available to administer the recommended dosage:

- 225 mg monthly, or
- 675 mg every 3 months (quarterly), which is administered as three consecutive subcutaneous injections of 225 mg each.

When switching dosage options, administer the first dose of the new regimen on the next scheduled date of administration. If a dose of AJOVY is missed, administer as soon as possible. Thereafter, AJOVY can be scheduled from the date of the last dose.

2.2 Important Administration Instructions

AJOVY is for subcutaneous use only.

AJOVY may be administered by healthcare professionals, patients, and/or caregivers. Prior to use, provide proper training to patients and/or caregivers on the preparation and administration of AJOVY prefilled syringe, including aseptic technique *[see Instructions for Use in full Prescribing Information]*.

- Remove AJOVY from the refrigerator. Prior to use, allow AJOVY to sit at room temperature for 30 minutes protected from direct sunlight. Do not warm by using a heat source such as hot water or a microwave. Do not use AJOVY if it has been at room temperature for 24 hours or longer.
- Follow aseptic injection technique every time AJOVY is administered.
- Inspect AJOVY for particles or discoloration prior to administration. Do not use if the solution is cloudy, discolored, or contains particles.
- Administer AJOVY by subcutaneous injection into areas of the abdomen, thigh, or upper arm that are not tender, bruised, red, or indurated. For multiple injections, you may use the same body site, but not the exact location of the previous injection.
- Do not co-administer AJOVY with other injectable drugs at the same injection site.

4 CONTRAINDICATIONS

AJOVY is contraindicated in patients with serious hypersensitivity to fremanezumab-vfrm or to any of the excipients *[see Warnings and Precautions (5.1)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

Hypersensitivity reactions, including rash, pruritus, drug hypersensitivity, and urticaria, were reported with AJOVY in clinical trials. Most reactions were mild to moderate, but some led to discontinuation or required corticosteroid treatment. Most reactions were reported from within hours to one month after administration.

If a hypersensitivity reaction occurs, consider discontinuing AJOVY, and institute appropriate therapy.

6 ADVERSE REACTIONS

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

- Hypersensitivity Reactions *[see Warnings and Precautions (5.1)]*

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 clinical practice.

The safety of AJOVY was evaluated in 2512 patients with migraine who received at least 1 dose of AJOVY, representing 1279 patient-years of exposure. Of these, 1730 patients were exposed to AJOVY 225 mg monthly or AJOVY 675 mg quarterly for at least 6 months, 775 patients for at least 12 months, and 138 patients for at least 15 months. In placebo-controlled clinical trials (Studies 1 and 2), 662 patients received AJOVY 225 mg monthly for 12 weeks (with or without a loading dose of 675 mg), and 663 patients received AJOVY 675 mg quarterly for 12 weeks. In the controlled trials, 87% of patients were female, 80% were White, and the mean age was 41 years.

The most common adverse reactions in the clinical trials for the preventive treatment of migraine (incidence at least 5% and greater than placebo) were injection site reactions. The adverse reactions that most commonly led to discontinuations were injection site reactions (1%). Table 1 summarizes adverse reactions reported in the 3-month placebo-controlled studies (Study 1 and Study 2), and the 1-month follow-up period after those studies.

Table 1: Adverse Reactions Occurring with an Incidence of At Least 2% for Either Dosing Regimen of AJOVY and At Least 2% Greater Than Placebo in Studies 1 and 2

Adverse Reaction	AJOVY 225 mg Monthly (n=290) %	AJOVY 675 mg Quarterly (n=667) %	Placebo Monthly (n=668) %
Injection site reactions[a]	43	45	38

[a] Injection site reactions include multiple related adverse event terms, such as injection site pain, induration, and erythema.

6.2 Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity. The detection of antibody formation is highly dependent on sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors, including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to fremanezumab-vfrm in the studies described below with the incidence of antibodies in other studies to other products may be misleading. Clinical immunogenicity of AJOVY was monitored by analyzing anti-drug antibodies (ADA) and neutralizing antibodies in drug-treated patients. The data reflect the percentage of patients whose test results were positive for antibodies to AJOVY in specific assays.

In 3-month placebo-controlled studies, treatment-emergent ADA responses were observed in 6 out of 1701 (0.4%) AJOVY-treated patients. One of the 6 patients developed anti-AJOVY neutralizing antibodies at Day 84. In the ongoing long-term open-label study, ADA were detected in 1.6% of patients (30 out of 1888). Out of 30 ADA-positive patients, 17 had a neutralizing activity in their post-dose samples. Although these data do not demonstrate an impact of anti-fremanezumab-vfrm antibody development on the efficacy or safety of AJOVY in these patients, the available data are too limited to make definitive conclusions.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate data on the developmental risk associated with the use of AJOVY in pregnant women. AJOVY has a long half-life. This should be taken into consideration for women who are pregnant or plan to become pregnant while using AJOVY. Administration of fremanezumab-vfrm to rats and rabbits during the period of organogenesis or to rats throughout pregnancy and lactation at doses resulting in plasma levels greater than those expected clinically did not result in adverse effects on development *[see Animal Data]*. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively. The estimated rate of major birth defects (2.2-2.9%) and miscarriage (17%) among deliveries to women with migraine are similar to rates reported in women without migraine.

Clinical Considerations

Disease-Associated Maternal and/or Embryo/Fetal Risk

Published data have suggested that women with migraine may be at increased risk of preeclampsia during pregnancy.

Data

Animal Data

When fremanezumab-vfrm (0, 50, 100, or 200 mg/kg) was administered to male and female rats by weekly subcutaneous injection prior to and during mating and continuing in females throughout organogenesis, no adverse embryofetal effects were observed. The highest dose tested was associated with plasma exposures (AUC) approximately 2 times that in humans at a dose of 675 mg.

Administration of fremanezumab-vfrm (0, 10, 50, or 100 mg/kg) weekly by subcutaneous injection to pregnant rabbits throughout the period of organogenesis produced no adverse effects on embryofetal development. The highest dose tested was associated with plasma AUC approximately 3 times that in humans (675 mg).

Administration of fremanezumab-vfrm (0, 50, 100, or 200 mg/kg) weekly by subcutaneous injection to female rats throughout pregnancy and lactation resulted in no adverse effects on pre- and postnatal development. The highest dose tested was associated with plasma AUC approximately 2 times that in humans (675 mg).

8.2 Lactation

Risk Summary

There are no data on the presence of fremanezumab-vfrm in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for AJOVY and any potential adverse effects on the breastfed infant from AJOVY or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

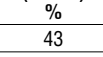
8.5 Geriatric Use

Clinical studies of AJOVY did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

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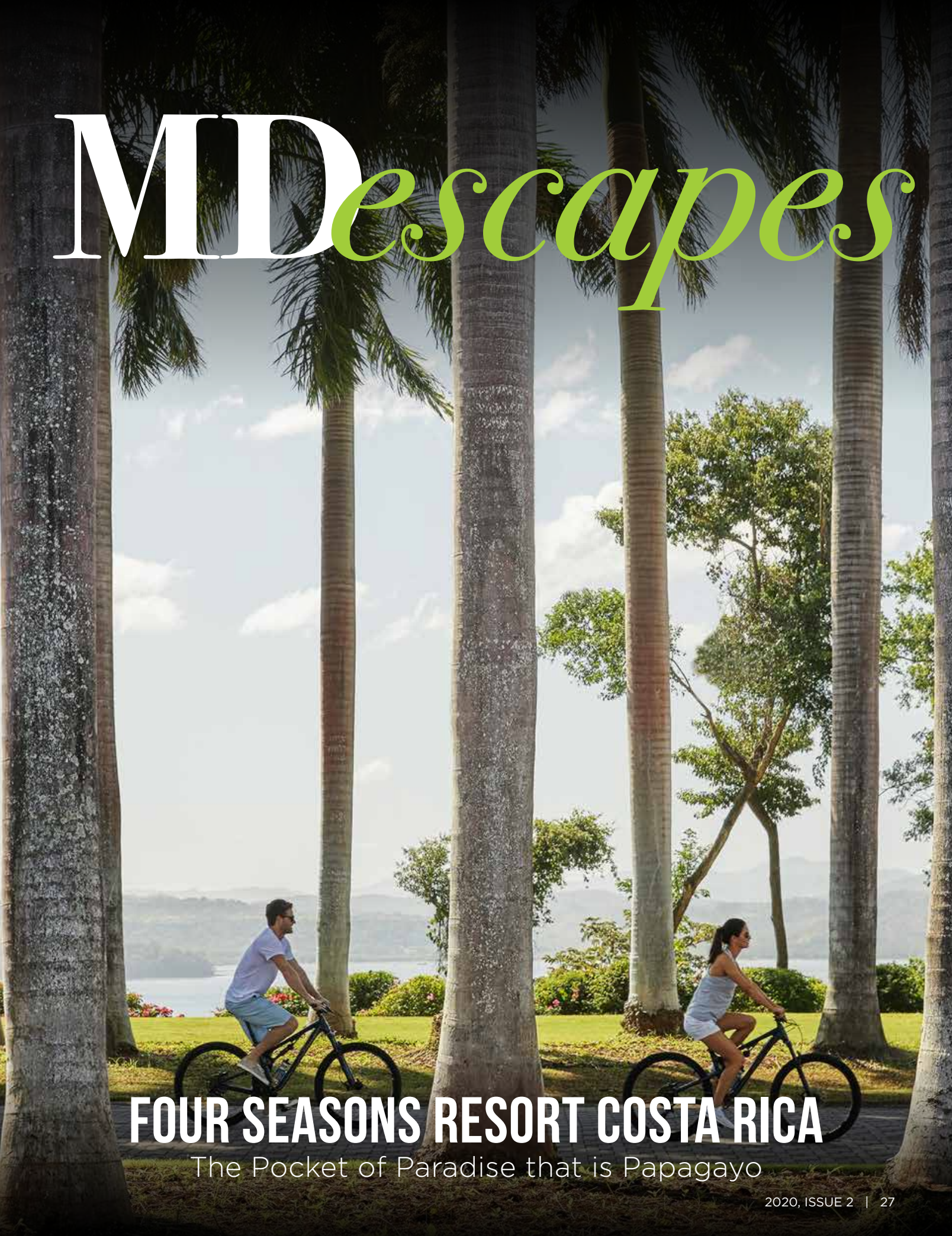
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This Brief Summary is based on the full Prescribing Information for AJOVY AJO-002.



FRE-41620 March 2019

MDescapes



FOUR SEASONS RESORT COSTA RICA

The Pocket of Paradise that is Papagayo



THE POCKET OF PARADISE THAT IS PAPAGAYO

Four Seasons Resort Costa Rica

BY BRANDI BROWER, TRAVEL EDITOR

"Pura Vida!" was my greeting as I stepped off the escalator at the Liberia airport, the driver offered to take my small carry-on and guided me into the waiting vehicle where a cold drink and chilled towel were offered to wipe away the air travel. The 30-minute drive passed by quickly as I appreciated the landscape of the Guanacaste Province, in a country that I had never been to before. As we made our way to the main entrance of the Papagayo Peninsula, I asked my driver to stop immediately. He didn't act surprised by my request, as I doubt that I was the first person who was struck by the breathtaking view from the top of the bluff. Equally striking, four large stone sculptures called Life Archipelago by Jorge Jimenez Deredia, a series of art pieces illustrating a drop of water turning into a woman holding the earth. Framed by a row of soaring palm trees, this served as a stunning gateway, welcoming me into a dream destination.

As we continued on the winding road, angulating up and down the small hills, I asked once again for the driver to stop the car. We were at the top of the incline just before the final descent, and there it was, the Four Seasons Resort Costa Rica, nestled in a verdant oasis. What makes this an exceptional slice of heaven is the positioning of the resort itself, perched on an isthmus, a narrow strip of land with sea on either side, forming a link between two more substantial pieces



of land. The resort takes advantage of this geographical gift, placing well-appointed villas and structures stretching across the landscape, granting the occupants the exceptional opportunity to enjoy both sunrise and sunset. If I hadn't suspected already, it hit me from this vantage point, that this was going to be a special place.

Tucked between two much larger peninsulas to the north and south, Papagayo Peninsula jets out on the West Coast side of the Central American country. It's just 1,400 acres of lush flora, formed by one of the volcanos in the region, 15 miles of coastline with its 31 beaches, 8 miles of bluffs, combine to makes this little strip of terra firma unforgettable.

Dylan greeted me with a tray holding a coconut with a straw and a cold towel infused with a refreshing scent. "Pura Vida," he proudly said with his big bright smile as he offered the pick-me-up. The relaxation had already begun as I familiarized myself with the stunning surroundings. Late 2017, the property unveiled a $35 million renovation, which transformed the hotel's indoor-outdoor spaces courtesy of NYC-based Meyer Davis Design Studio. The redesigned lobby with a natural soothing palette embraces me. Still, my eyes are drawn toward the concierge lounge, where a moss art wall is juxtaposed with interactive screens showcasing the numerous adventure options available for the guests to explore. The Papagayo Explorers Club provides 25 exclusive aerial, land, ocean, and cultural immersion "only here" adventures like a guided naturalist hike via 4x4 vehicles to a protected crater of an inactive volcano. I have never called myself an eco-adventurer, but there is something transformative about this unique corner of the world. So sign me up!

I quickly realized that I had a problem. The math didn't compute. I had "X" number of waking hours at the Four Seasons Resort, and I wanted to know "Y" there wasn't a solution for how I could stay at this fantastic place even longer. For example, I'll share just a fraction of the weekly resort activities that are complementary or with a small fee. Guests may want to try a Healthy Juice Class, Bird watching tour, Pura Vista Climb, Full Swing Golf Clinic, Tennis Doubles Clinic, Latin Dance Class, Beach Volleyball, Paddle board tour, Mangrove Walk, Beach Soccer. There is even a weekly opportunity to give service to the local community. I'm barely scratching the surface, listing just a dozen of the numerous activities provided by the resort for your enjoyment — not enough hours in the day, not enough days in the week. But I'm anxious to get started.

The golf cart carries me up, up, up the pathway to my one-bedroom canopy suite. The stilted structure is nestled into the mountain side, designed to blend into the surroundings perfectly. But then that was the goal. Renowned Costa Rican architect, Ronald Zürcher Gurdian, didn't want to compete with nature, he tried to compliment it when he set out to design this Four Seasons jungle retreat. Zrcher sought out inspiration all around him in the animals, trees, birds, and butterflies. Many of the low-lying buildings at the resort mimic the dramatic features of the countries famous creatures: the upward slope of a butterfly's wings, the armadillo's humped back, and the turtle's rounded shell are all represented in the rooflines. The designer studied these animals to spark creativity. He observed how armadillos walk in their families, one after another. Rather than build one large, single roof, he designed the roofs in pieces, each in the shape of a single armadillo, so that from a distance it looks like a family of the little creatures. The architect was serious in his endeavor to camouflage his alluring creation, going as far as sending Papagayo dirt to a paint laboratory so that his buildings would synthesize with the ground beneath them.

The interiors lend a feeling of flow, relying on simplicity. Allows one to pass outside to inside with an equal sense of tranquility and calm. Like the rest of the resort aesthetic, the expansive suite's decor is bright and airy, white on cream walls and textiles, rattan and light woods with several stylish vanguard pieces to modernize the space. Marble bathrooms, double vanities, deep tubs with separate showers, comfortable linens on the infamous Four Seasons mattresses. Luxury is never compromised. Attached to the bridge walkway leading to my suite is a large covered terrace with a double chaise cushioned lounge chair beckoning to be sat upon, which I did enjoy on the daily — best of all, the views. The well-placed configuration of the 182 guest rooms and suites afford each lucky patron picturesque views of the ocean, jungle, or a combination of both. Who needs the "Calm" app with soothing sounds of nature as a slumber aid when you can open up your large sliding doors and be lulled to sleep by the real thing?

What makes this an exceptional slice of heaven is the positioning of the resort itself, perched on an isthmus, a narrow strip of land with sea on either side, forming a link between two more substantial pieces of land.

Natural light poured into my bedroom signaling a new day. I reached for my phone to take a half dozen pictures of the emerging sun rising over the bay. Just when I thought it couldn't become any more brilliant, it changed again and I quickly snapped another photo to capture this serene scene. What an incredible country! Even more incredible is the forethought that went into the planning by the Costa Rican government more than 3o years ago to recognize this gorgeous geography as a place where tourism would flourish. This small Latin American gem hosts a priceless ecosystem, one of the last dry tropical forests on the earth. Costa Rica has been ahead of the curve with their early pursuit of a national zero carbon footprint. Almost 100% of the small country, its size comparable to the state of West Virginia, obtains its energy from renewable sources. They were green long before being green was cool. A country that occupies .03% the globe's surface but accounts for almost 5% of the biodiversity on the planet. The vision of protecting their land from deforestation and farming, Costa Rica deemed 30% their property officially protected, classifying most as reserves and national parks, in comparison to the U.S. that protects just 13%.





Costa Rican's early green philosophy and protection of their precious land resources have indeed brought the tourists. Those seeking adventure in a land bursting with wildlife, Guanacaste Province is the perfect place to visit. If you want outdoor adventure with a sprinkle or perhaps a heavy heaping of luxury, you can be satisfied with both at the Four Seasons Resort Peninsula Papagayo. There is no reason for roughing it when you can enjoy the amazing amenities that this award-winning property provides. You can have your Tres Leches cake and eat it too!

I couldn't possibly conquer all the activities afforded me during my visit, but I was going to try. I started the day with an Acai bowl at Anejo to get some energy. I bypassed a work out in the extensive fitness center filled with Technogym equipment and opted for a 7:45 a.m. spin class, which was taught outside, with an ocean view. If you have to break a sweat, at least enjoy looking at beautiful waves while burning calories.

I decided the best way to see the gorgeous peninsula was by bike. With the Papagayo bike-share program, a fleet of electric-assist bikes made it easier to explore the very hilly terrain. The scenery is breathtaking all along the route, stopping at particular points to take in the incredible vistas. I made my way down to Marina Village, which overlooked the Culebra Bay and home to the 180-slip superyacht marina and decided I'd park my bike in a charging station and called for the resort to pick me up. While I waited, I enjoyed some of the best chips and guacamole I've ever had at the Dive Bar.

I'm a spa girl at heart. I knew that one of my priorities during my stay would be to take advantage of some of the many transcendental treatments offered to get my zen on. The Wellness Center has several natural restorative rituals drawing from ancient healing traditions from around the world like Turkish hammam bath, Reiki, sound healing, Abhyanga massage, and aromatherapy. Both hot and cold hydrotherapy pools are on an elevated veranda overlooking the beach below. Wrapped in a comfy white robe, I sat in the lovely pre-treatment relaxation lounge, waiting to be escorted to the Playa Virador room for my Natural Healing Bamboo massage. I enjoyed it so much that I knew I'd be back tomorrow. Afterward I was taken to one of the post treatment private indoor cabanas which had a cozy chase lounge. As I sipped on a glass of Agua de Sapo, a traditional Costa Rican drink made of ginger, sugar cane, and lemon, I soaked in all of the self-care indulgences of the afternoon. Waterfall showers, sauna and steam rooms, body wraps and scrubs, facials, foot treatments, hair and nail salon services. A gal could get pretty spoiled here.

The day was still young, and I felt just a bit younger thanks to the Wellness Center. So I decided to tackle snorkeling. The resort is flanked on either side by two beautiful beaches, Playa Blanca, which is on the Culebra Bay is where guests gather to enjoy all non-motorized sports. Playa Virador on the Gulf of Papagayo is for relaxation with cabanas and loungers spread across the white sand. Located on the Pacific side, it makes for the perfect place for end-of-day libations and sunset selfies. After being fitted at the activities center on the beach, I donned my fins and snorkel intending to make it out to Monkey Head Rock (it looks just like a monkey's head), but I gave up, blaming it on the spin class and the bike ride.

I returned the equipment and decided I'd relax poolside. There are four. The first pool, one-foot in depth, is designated for small children, with adorable, pint-sized, blue, and white broad stripped pool loungers on the large patio, which is attached to the complimentary Kids for All Seasons program. Uniquely Four Seasons, they offer daily supervised activities like face painting, puppet making, nature walks, and building sandcastles, all for children 4 to 12. It has a Foosball game, mini-basketball hoop, computers, Nintendo Wii, toys, and games. For the older crowd, Tuanis, the teen center, offers a separate place for 12 - 16-year-olds to hang out. Along with video and computer games, the center hosts themed parties and movies on the lawn.

The Serena pool is the adult-only quiet pool, with draped cabanas for privacy and just feet away from the quiet beach, Playa Virador. The Blanca pool is the lively pool just steps from the activities beach where families like to gather. I chose the Bahia pool, in between the others, the heart of the resort, it's a 10,000 square foot freshwater pool and a grotto whirlpool. With abundant chaise lounge chairs, umbrellas, and attendants offering complimentary sunblock, aloe vera, fruit, flavored waters, and yummy treats, it was an excellent place for me to unwind from all of my unwindings.

La Reserva is reserved for socializing. This very cool aesthetic, sophisticated vibe where infused rum tastings, rum & chocolate tastings, mixology classes, coffee classes, wildlife lectures, and trivia sessions happen all week on the daily — a great place to go when a quick tropical downpour catches you by surprise.

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REALIZE THE POTENTIAL



Choose Ozempic® as your first injectable— the only once-weekly GLP-1 RA with superior results vs Trulicity®[1,2]

SUPERIOR GLYCEMIC CONTROL

SUPERIOR WEIGHT REDUCTION

Ozempic® is not indicated for weight loss.

CV SAFETY

as evaluated in a 2-year CVOT.[2]

Ozempic® is not indicated for reduction in major adverse CV events (MACE).

SUSTAIN 6: A 2-year, randomized, multinational, double-blind, placebo-controlled, parallel-group CV safety trial that was designed to assess noninferiority of Ozempic® vs standard of care by excluding the preapproval noninferiority margin of 1.8. A total of 3297 adult patients with type 2 diabetes and high risk of CV events were randomized based on evidence of CV disease, insulin treatment, and renal impairment to once-weekly Ozempic® 0.5 mg (n=826), Ozempic® 1 mg (n=822), or placebo (n=1649) in addition to standard of care treatments such as oral antidiabetic treatments, insulin, antihypertensives, diuretics, lipid-lowering therapies, and antithrombotic medication at investigator discretion. The primary composite endpoint was the time from randomization to first occurrence of a MACE, defined as CV death, nonfatal myocardial infarction, or nonfatal stroke.[3]

Indication and Limitations of Use

Ozempic® (semaglutide) injection 0.5 mg or 1 mg is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

- Ozempic® is not recommended as a first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of rodent C-cell tumor findings to humans.
- Ozempic® has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Ozempic® is not a substitute for insulin. Ozempic® is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of patients with diabetic ketoacidosis.

Important Safety Information

WARNING: RISK OF THYROID C-CELL TUMORS

- **In rodents, semaglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether Ozempic® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined.**
- **Ozempic® is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of Ozempic® and inform them of symptoms of thyroid tumors (e.g. a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Ozempic®.**

Contraindications

- Ozempic® is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2, and in patients with known hypersensitivity to semaglutide or to any of the product components.

Warnings and Precautions

- **Risk of Thyroid C-Cell Tumors:** Patients should be referred to an endocrinologist for further evaluation if serum calcitonin is measured and found to be elevated or thyroid nodules are noted on physical examination or neck imaging.
- **Pancreatitis:** Acute and chronic pancreatitis have been reported in clinical studies. Observe patients carefully for signs and symptoms of pancreatitis (persistent severe abdominal pain, sometimes radiating to the back with or without vomiting). If pancreatitis is suspected, discontinue Ozempic® promptly, and if pancreatitis is confirmed, do not restart.
- **Diabetic Retinopathy Complications:** In a 2-year trial involving patients with type 2 diabetes and high cardiovascular risk, more events of diabetic retinopathy complications occurred in patients treated with Ozempic® (3.0%) compared to placebo (1.8%). The absolute risk increase for diabetic retinopathy complications was larger among patients with a history of diabetic retinopathy at baseline than among patients without a known history of diabetic retinopathy.

  Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. The effect of long-term glycemic control with semaglutide on diabetic retinopathy complications has not been studied. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy.

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In a 40-week trial, in patients on metformin, for each dose comparison

Ozempic® was superior to Trulicity® in A1C and weight reduction[1]

ONCE-WEEKLY OZEMPIC® semaglutide injection 0.5mg|1mg



Ozempic® outperformed Trulicity® in reducing A1C[1]

–1.4% with **Ozempic® 0.5 mg** (Baseline: 8.3%) vs
–1.1% with **Trulicity® 0.75 mg** (Baseline: 8.2%); *P*=0.002

–1.6% with **Ozempic® 1 mg** (Baseline: 8.2%) vs
–1.3% with **Trulicity® 1.5 mg** (Baseline: 8.2%); *P*=0.0004



Secondary endpoint

Ozempic® demonstrated superior body weight reduction vs Trulicity®[1]

Ozempic® is not indicated for weight loss.

–9.3 lb with **Ozempic® 0.5 mg** (Baseline: 213 lb) vs
–4.6 lb with **Trulicity® 0.75 mg** (Baseline: 211 lb); ETD=–4.7 lb (95% CI; –6.5, –2.9)

–12.8 lb with **Ozempic® 1 mg** (Baseline: 211 lb) vs
–6.2 lb with **Trulicity® 1.5 mg** (Baseline: 206 lb); ETD=–6.7 lb (95% CI; –8.5, –5.0)

SUSTAIN 7: A 40-week, multinational, multicenter, randomized, open-label, four-armed, pair-wise, active-controlled, parallel-group trial to compare the efficacy and safety of Ozempic® vs dulaglutide. A total of 1201 adult patients with type 2 diabetes inadequately controlled on metformin were randomized to receive Ozempic® 0.5 mg (n=301), Ozempic® 1 mg (n=300), dulaglutide 0.75 mg (n=299), or dulaglutide 1.5 mg (n=299) once weekly. The primary endpoint was mean change in A1C from baseline at Week 40. Secondary endpoints included mean change in body weight at Week 40 and proportion of patients achieving A1C <7% at Week 40. Results based on a sensitivity analysis of retrieved dropout population.[1]

Learn more about Ozempic® and the CVOT at ***OzempicPro.com***.

- **Never Share an Ozempic® Pen Between Patients:** Ozempic® pens must never be shared between patients, even if the needle is changed. Pen-sharing poses a risk for transmission of blood-borne pathogens.
- **Hypoglycemia:** The risk of hypoglycemia is increased when Ozempic® is used in combination with insulin secretagogues (e.g., sulfonylureas) or insulin.
- **Acute Kidney Injury:** There have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis, in patients treated with GLP-1 receptor agonists. Some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function when initiating or escalating doses of Ozempic® in patients reporting severe adverse gastrointestinal reactions.
- **Hypersensitivity:** Serious hypersensitivity reactions (e.g., anaphylaxis, angioedema) have been reported with GLP-1 receptor agonists. If hypersensitivity reactions occur, discontinue use of Ozempic®; treat promptly per standard of care, and monitor until signs and symptoms resolve. Use caution in a patient with a history of angioedema or anaphylaxis with another GLP-1 receptor agonist.
- **Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with Ozempic®.

Adverse Reactions

- The most common adverse reactions, reported in ≥5% of patients treated with Ozempic® are nausea, vomiting, diarrhea, abdominal pain, and constipation.

Drug Interactions

- The risk of hypoglycemia may be lowered by a reduction in the dose of the secretagogue or insulin.
- Ozempic® causes a delay of gastric emptying and has the potential to impact the absorption of concomitantly administered oral medications, so caution should be exercised.

Use in Specific Populations

- There are limited data with semaglutide use in pregnant women to inform a drug-associated risk for adverse developmental outcomes. Discontinue Ozempic® in women at least 2 months before a planned pregnancy due to the long washout period for semaglutide.

Please see Brief Summary of Prescribing Information on following pages.

GLP-1 RA=glucagon-like peptide-1 receptor agonist; CV=cardiovascular; CVOT=cardiovascular outcomes trial; ETD=estimated treatment difference; CI=confidence interval.

References: 1. Pratley RE, Aroda VR, Lingvay I, et al. Semaglutide versus dulaglutide once weekly in patients with type 2 diabetes (SUSTAIN 7): a randomised, open-label, phase 3b trial. *Lancet Diabetes Endocrinol.* 2018;6(4):275-286. **2.** Ozempic [package insert]. Plainsboro, NJ: Novo Nordisk Inc; 2017. **3.** Marso SP, Bain SC, Consoli A, et al. Semaglutide and cardiovascular outcomes in patients with type 2 diabetes. *N Engl J Med.* 2016;375(19):1834-1844.

ONCE-WEEKLY OZEMPIC® semaglutide injection 0.5mg|1mg

OZEMPIC® (semaglutide) injection

Rx Only

BRIEF SUMMARY: Please consult package insert for full prescribing information.

WARNING: RISK OF THYROID C-CELL TUMORS: In rodents, semaglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether OZEMPIC® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined *[see Warnings and Precautions]*. OZEMPIC® is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2) *[see Contraindications]*. Counsel patients regarding the potential risk for MTC with the use of OZEMPIC® and inform them of symptoms of thyroid tumors (e.g. a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with OZEMPIC® *[see Contraindications and Warnings and Precautions]*.

INDICATIONS AND USAGE: OZEMPIC® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: OZEMPIC® is not recommended as a first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of rodent C-cell tumor findings to humans *[see Warnings and Precautions]*. OZEMPIC® has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis *[see Warnings and Precautions]*. OZEMPIC® is not a substitute for insulin. OZEMPIC® is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of patients with diabetic ketoacidosis, as it would not be effective in these settings.

CONTRAINDICATIONS: OZEMPIC® is contraindicated in patients with: A personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2) *[see Warnings and Precautions]*; Known hypersensitivity to semaglutide or to any of the product components *[see Warnings and Precautions]*.

WARNINGS AND PRECAUTIONS: Risk of Thyroid C-Cell Tumors: In mice and rats, semaglutide caused a dose-dependent and treatment-duration-dependent increase in the incidence of thyroid C-cell tumors (adenomas and carcinomas) after lifetime exposure at clinically relevant plasma exposures. It is unknown whether OZEMPIC® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined. Cases of MTC in patients treated with liraglutide, another GLP-1 receptor agonist, have been reported in the postmarketing period; the data in these reports are insufficient to establish or exclude a causal relationship between MTC and GLP-1 receptor agonist use in humans. OZEMPIC® is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2. Counsel patients regarding the potential risk for MTC with the use of OZEMPIC® and inform them of symptoms of thyroid tumors (e.g. a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with OZEMPIC®. Such monitoring may increase the risk of unnecessary procedures, due to the low test specificity for serum calcitonin and a high background incidence of thyroid disease. Significantly elevated serum calcitonin value may indicate MTC and patients with MTC usually have calcitonin values >50 ng/L. If serum calcitonin is measured and found to be elevated, the patient should be further evaluated. Patients with thyroid nodules noted on physical examination or neck imaging should also be further evaluated. **Pancreatitis:** In glycemic control trials, acute pancreatitis was confirmed by adjudication in 7 OZEMPIC®-treated patients (0.3 cases per 100 patient years) versus 3 in comparator-treated patients (0.2 cases per 100 patient years). One case of chronic pancreatitis was confirmed in an OZEMPIC®-treated patient. In a 2-year trial, acute pancreatitis was confirmed by adjudication in 8 OZEMPIC®-treated patients (0.27 cases per 100 patient years) and 10 placebo-treated patients (0.33 cases per 100 patient years), both on a background of standard of care. After initiation of OZEMPIC®, observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back and which may or may not be accompanied by vomiting). If pancreatitis is suspected, OZEMPIC® should be discontinued and appropriate management initiated; if confirmed, OZEMPIC® should not be restarted. **Diabetic Retinopathy Complications:** In a 2-year trial involving patients with type 2 diabetes and high cardiovascular risk, more events of diabetic retinopathy complications occurred in patients treated with OZEMPIC® (3.0%) compared to placebo (1.8%). The absolute risk increase for diabetic retinopathy complications was larger among patients with a history of diabetic retinopathy at baseline (OZEMPIC® 8.2%, placebo 5.2%) than among patients without a known history of diabetic retinopathy (OZEMPIC® 0.7%, placebo 0.4%). Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. The effect of long-term glycemic control with semaglutide on diabetic retinopathy complications has not been studied. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy. **Never Share an OZEMPIC® Pen Between Patients:** OZEMPIC® pens must never be shared between patients, even if the needle is changed. Pen-sharing poses a risk for transmission of blood-borne pathogens. **Hypoglycemia with Concomitant Use of Insulin Secretagogues or Insulin:** The risk of hypoglycemia is increased when OZEMPIC® is used in combination with insulin secretagogues (e.g., sulfonylureas) or insulin. Patients may require a lower dose of the secretagogue or insulin to reduce the risk of hypoglycemia in this setting *[see Adverse Reactions, Drug Interactions]*. **Acute Kidney Injury:** There have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis, in patients treated with GLP-1 receptor agonists. Some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function when initiating or escalating doses of OZEMPIC® in patients reporting severe adverse gastrointestinal reactions. **Hypersensitivity:** Serious hypersensitivity reactions (e.g., anaphylaxis, angioedema) have been reported with GLP-1 receptor agonists. If hypersensitivity reactions occur, discontinue use of OZEMPIC®; treat promptly per standard of care, and monitor until signs and symptoms resolve. Do not use in patients with a previous hypersensitivity to OZEMPIC® *[see Contraindications]*. Anaphylaxis and angioedema have been reported with other GLP-1 receptor agonists. Use caution in a patient with a history of angioedema or anaphylaxis with another GLP-1 receptor agonist because it is unknown whether such patients will be predisposed to anaphylaxis with OZEMPIC®. **Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with OZEMPIC®.

ADVERSE REACTIONS: The following serious adverse reactions are described below or elsewhere in the prescribing information: Risk of Thyroid C-cell Tumors *[see Warnings and Precautions]*; Pancreatitis *[see Warnings and Precautions]*; Diabetic Retinopathy Complications *[see Warnings and Precautions]*; Hypoglycemia with Concomitant Use of Insulin Secretagogues or Insulin *[see Warnings and Precautions]*; Acute Kidney Injury *[see Warnings and Precautions]*; Hypersensitivity *[see Warnings and Precautions]*. **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. Pool of Placebo-Controlled Trials: The data in Table 1 are derived from 2 placebo-controlled trials (1 monotherapy trial and 1 trial in combination with basal insulin) in patients with type 2 diabetes. These data reflect exposure of 521 patients to OZEMPIC® and a mean duration of exposure to OZEMPIC® of 32.9 weeks. Across the treatment arms, the mean age of patients was 56 years, 3.4% were 75 years or older and 55% were male. In these trials 71% were White, 7% were Black or African American, and 19% were Asian; 21% identified as Hispanic or Latino ethnicity. At baseline, patients had type 2 diabetes for an average of 8.8 years and had a mean HbA_{1c} of 8.2%. At baseline, 8.9% of the population reported retinopathy. Baseline estimated renal function was normal (eGFR ≥90 mL/min/1.73m^2) in 57.2%, mildly impaired (eGFR 60 to 90 mL/min/1.73m^2) in 35.9% and moderately impaired (eGFR 30 to 60 mL/min/1.73m^2) in 6.9% of patients. Pool of Placebo- and Active-Controlled Trials: The occurrence of adverse reactions was also evaluated in a larger pool of patients with type 2 diabetes participating in 7 placebo- and active-controlled glycemic control trials including two trials in Japanese patients evaluating the use of OZEMPIC® as monotherapy and add-on therapy to oral medications or insulin. In this pool, a total of 3150 patients with type 2 diabetes were treated with OZEMPIC® for a mean duration of 44.9 weeks. Across the treatment arms, the mean age of patients was 57 years, 3.2% were 75 years or older and 57% were male. In these trials, 60% were White, 6% were Black or African American, and 31% were Asian; 16% identified as Hispanic or Latino ethnicity. At baseline, patients had type 2 diabetes for an average of 8.2 years and had a mean HbA_{1c} of 8.2%. At baseline, 7.8% of the population reported retinopathy. Baseline estimated renal function was normal (eGFR ≥90 mL/min/1.73m^2) in 63.1%, mildly impaired (eGFR 60 to 90 mL/min/1.73m^2) in 34.3%, and moderately impaired (eGFR 30 to 60 mL/min/1.73m^2) in 2.5% of the patients. Common Adverse Reactions: Table 1 shows common adverse reactions, excluding hypoglycemia, associated with the use of OZEMPIC® in the pool of placebo-controlled trials. These adverse reactions occurred more commonly on OZEMPIC® than on placebo, and occurred in at least 5% of patients treated with OZEMPIC®.

Table 1. Adverse Reactions in Placebo-Controlled Trials Reported in ≥5% of OZEMPIC®-Treated Patients with Type 2 Diabetes Mellitus

Adverse Reaction	Placebo (N=262) %	OZEMPIC® 0.5 mg (N=260) %	OZEMPIC® 1 mg (N=261) %
Nausea	6.1	15.8	20.3
Vomiting	2.3	5.0	9.2
Diarrhea	1.9	8.5	8.8
Abdominal pain	4.6	7.3	5.7
Constipation	1.5	5.0	3.1

In the pool of placebo- and active-controlled trials and in the 2-year cardiovascular outcomes trial, the types and frequency of common adverse reactions, excluding hypoglycemia, were similar to those listed in Table 1. *Gastrointestinal Adverse Reactions:* In the pool of placebo-controlled trials, gastrointestinal adverse reactions occurred more frequently among patients receiving OZEMPIC® than placebo (placebo 15.3%, OZEMPIC® 0.5 mg 32.7%, OZEMPIC® 1 mg 36.4%). The majority of reports of nausea, vomiting, and/or diarrhea occurred during dose escalation. More patients receiving OZEMPIC® 0.5 mg (3.1%) and OZEMPIC® 1 mg (3.8%) discontinued treatment due to gastrointestinal adverse reactions than patients receiving placebo (0.4%). In addition to the reactions in Table 1, the following gastrointestinal adverse reactions with a frequency of <5% were associated with OZEMPIC® (frequencies listed, respectively, as: placebo; 0.5 mg; 1 mg): dyspepsia (1.9%, 3.5%, 2.7%), eructation (0%, 2.7%, 1.1%), flatulence (0.8%, 0.4%, 1.5%), gastroesophageal reflux disease (0%, 1.9%, 1.5%), and gastritis (0.8%, 0.8%, 0.4%). Other Adverse Reactions: *Hypoglycemia:* Table 2 summarizes the incidence of events related to

hypoglycemia by various definitions in the placebo-controlled trials.

Table 2. Hypoglycemia Adverse Reactions in Placebo-Controlled Trials In Patients with Type 2 Diabetes Mellitus

	Placebo	OZEMPIC® 0.5 mg	OZEMPIC® 1 mg
Monotherapy			
(30 weeks)	**N=129**	**N=127**	**N=130**
Severe†	0%	0%	0%
Documented symptomatic (≤70 mg/dL glucose threshold)	0%	1.6%	3.8%
Severe† or Blood Glucose Confirmed Symptomatic (≤56 mg/dL glucose threshold)	1.6%	0%	0%
Add-on to Basal Insulin with or without Metformin			
(30 weeks)	**N=132**	**N=132**	**N=131**
Severe†	0%	0%	1.5%
Documented symptomatic (≤70 mg/dL glucose threshold)	15.2%	16.7%	29.8%
Severe† or Blood Glucose Confirmed Symptomatic (≤56 mg/dL glucose threshold)	5.3%	8.3%	10.7%

†"Severe" hypoglycemia adverse reactions are episodes requiring the assistance of another person.

Hypoglycemia was more frequent when OZEMPIC® was used in combination with a sulfonylurea *[see Warnings and Precautions]*. Severe hypoglycemia occurred in 0.8% and 1.2% of patients when OZEMPIC® 0.5 mg and 1 mg, respectively, was co-administered with a sulfonylurea. Documented symptomatic hypoglycemia occurred in 17.3% and 24.4% of patients when OZEMPIC® 0.5 mg and 1 mg, respectively, was co-administered with a sulfonylurea. Severe or blood glucose confirmed symptomatic hypoglycemia occurred in 6.5% and 10.4% of patients when OZEMPIC® 0.5 mg and 1 mg, respectively, was co-administered with a sulfonylurea. Injection Site Reactions: In placebo-controlled trials, injection site reactions (e.g., injection-site discomfort, erythema) were reported in 0.2% of OZEMPIC®-treated patients. Increases in Amylase and Lipase: In placebo-controlled trials, patients exposed to OZEMPIC® had a mean increase from baseline in amylase of 13% and lipase of 22%. These changes were not observed in placebo-treated patients. Cholelithiasis: In placebo-controlled trials, cholelithiasis was reported in 1.5% and 0.4% of patients-treated with OZEMPIC® 0.5 mg and 1 mg, respectively. Cholelithiasis was not reported in placebo-treated patients. Increases in Heart Rate: In placebo-controlled trials, OZEMPIC® 0.5 mg and 1 mg resulted in a mean increase in heart rate of 2 to 3 beats per minute. There was a mean decrease in heart rate of 0.3 beats per minute in placebo-treated patients. Fatigue, Dysgeusia and Dizziness: Other adverse reactions with a frequency of >0.4% were associated with OZEMPIC® include fatigue, dysgeusia and dizziness. **Immunogenicity:** Consistent with the potentially immunogenic properties of protein and peptide pharmaceuticals, patients treated with OZEMPIC® may develop anti-semaglutide antibodies. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, the incidence of antibodies to semaglutide in the studies described below cannot be directly compared with the incidence of antibodies in other studies or to other products. Across the placebo- and active-controlled glycemic control trials, 32 (1.0%) OZEMPIC®-treated patients developed anti-drug antibodies (ADAs) to the active ingredient in OZEMPIC® (i.e., semaglutide). Of the 32 semaglutide-treated patients that developed semaglutide ADAs, 19 patients (0.6% of the overall population) developed antibodies cross-reacting with native GLP-1. The in vitro neutralizing activity of the antibodies is uncertain at this time.

DRUG INTERACTIONS: Concomitant Use with an Insulin Secretagogue (e.g., Sulfonylurea) or with Insulin: The risk of hypoglycemia is increased when OZEMPIC® is used in combination with insulin secretagogues (e.g., sulfonylureas) or insulin. The risk of hypoglycemia may be lowered by a reduction in the dose of sulfonylurea (or other concomitantly administered insulin secretagogues) or insulin *[see Warnings and Precautions]*. **Oral Medications:** OZEMPIC® causes a delay of gastric emptying, and thereby has the potential to impact the absorption of concomitantly administered oral medications. In clinical pharmacology trials, semaglutide did not affect the absorption of orally administered medications to any clinically relevant degree. Nonetheless, caution should be exercised when oral medications are concomitantly administered with OZEMPIC®.

USE IN SPECIFIC POPULATIONS: Pregnancy: Risk Summary: There are limited data with semaglutide use in pregnant women to inform a drug-associated risk for adverse developmental outcomes. There are clinical considerations regarding the risks of poorly controlled diabetes in pregnancy *(see Clinical Considerations)*. Based on animal reproduction studies, there may be potential risks to the fetus from exposure to semaglutide during pregnancy. OZEMPIC® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. In pregnant rats administered semaglutide during organogenesis, embryofetal mortality, structural abnormalities and alterations to growth occurred at maternal exposures below the maximum recommended human dose (MRHD) based on AUC. In rabbits and cynomolgus monkeys administered semaglutide during organogenesis, early pregnancy losses and structural abnormalities were observed at below the MRHD (rabbit) and ≥5-fold the MRHD (monkey). These findings coincided with a marked maternal body weight loss in both animal species *(see Data)*. The estimated background risk of major birth defects is 6–10% in women with pre-gestational diabetes with an HbA_{1c} >7 and has been reported to be as high as 20–25% in women with a HbA_{1c} >10. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively. Clinical Considerations: *Disease associated maternal and fetal risk:* Poorly controlled diabetes during pregnancy increases the maternal risk for diabetic ketoacidosis, pre-eclampsia, spontaneous abortions, preterm delivery, stillbirth and delivery complications. Poorly controlled diabetes increases the fetal risk for major birth defects, stillbirth, and macrosomia related morbidity. Data: *Animal Data:* In a combined fertility and embryofetal development study in rats, subcutaneous doses of 0.01, 0.03 and 0.09 mg/kg/day (0.1-, 0.4-, and 1.1-fold the MRHD) were administered to males for 4 weeks prior to and throughout mating and to females for 2 weeks prior to mating, and throughout organogenesis to Gestation Day 17. In parental animals, pharmacologically mediated reductions in body weight gain and food consumption were observed at all dose levels. In the offspring, reduced growth and fetuses with visceral (heart blood vessels) and skeletal (cranial bones, vertebra, ribs) abnormalities were observed at the human exposure. In an embryofetal development study in pregnant rabbits, subcutaneous doses of 0.0010, 0.0025 or 0.0075 mg/kg/day (0.03-, 0.3-, and 2.3-fold the MRHD) were administered throughout organogenesis from Gestation Day 6 to 19. Pharmacologically mediated reductions in maternal body weight gain and food consumption were observed at all dose levels. Early pregnancy losses and increased incidences of minor visceral (kidney, liver) and skeletal (sternebra) fetal abnormalities were observed at ≥0.0025 mg/kg/day, at clinically relevant exposures. In an embryofetal development study in pregnant cynomolgus monkeys, subcutaneous doses of 0.015, 0.075, and 0.15 mg/kg twice weekly (1.0-, 5.2-, and 14.9-fold the MRHD) were administered throughout organogenesis, from Gestation Day 16 to 50. Pharmacologically mediated, marked initial maternal body weight loss and reductions in body weight gain and food consumption coincided with the occurrence of sporadic abnormalities (vertebra, sternebra, ribs) at ≥0.075 mg/kg twice weekly (≥5X human exposure). In a pre- and postnatal development study in pregnant cynomolgus monkeys, subcutaneous doses of 0.015, 0.075, and 0.15 mg/kg twice weekly (0.7-, 3.3-, and 7.2-fold the MRHD) were administered from Gestation Day 16 to 140. Pharmacologically mediated marked initial maternal body weight loss and reductions in body weight gain and food consumption coincided with an increase in early pregnancy losses and led to delivery of slightly smaller offspring at ≥0.075 mg/kg twice weekly (≥3X human exposure). **Lactation:** Risk Summary: There are no data on the presence of semaglutide in human milk, the effects on the breastfed infant, or the effects on milk production. Semaglutide was present in the milk of lactating rats, however, due to species-specific differences in lactation physiology, the clinical relevance of these data are not clear *(see Data)*. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for OZEMPIC® and any potential adverse effects on the breastfed infant from OZEMPIC® or from the underlying maternal condition. Data: In lactating rats, semaglutide was detected in milk at levels 3-12 fold lower than in maternal plasma. **Females and Males of Reproductive Potential:** Discontinue OZEMPIC® in women at least 2 months before a planned pregnancy due to the long washout period for semaglutide *[see Use in Specific Populations]*. **Pediatric Use:** Safety and efficacy of OZEMPIC® have not been established in pediatric patients (younger than 18 years). **Geriatric Use:** In the pool of placebo- and active-controlled glycemic control trials, 744 (23.6%) OZEMPIC®-treated patients were 65 years of age and over and 102 OZEMPIC®-treated patients (3.2%) patients were 75 years of age and over. In SUSTAIN 6, the cardiovascular outcome trial, 788 (48.0%) OZEMPIC®-treated patients were 65 years of age and over and 157 OZEMPIC®-treated patients (9.6%) patients were 75 years of age and over. No overall differences in safety or efficacy were detected between these patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out. **Renal Impairment:** No dose adjustment of OZEMPIC® is recommended for patients with renal impairment. In subjects with renal impairment including end-stage renal disease (ESRD), no clinically relevant change in semaglutide pharmacokinetics (PK) was observed. **Hepatic Impairment:** No dose adjustment of OZEMPIC® is recommended for patients with hepatic impairment. In a study in subjects with different degrees of hepatic impairment, no clinically relevant change in semaglutide pharmacokinetics (PK) was observed.

OVERDOSAGE: In the event of overdose, appropriate supportive treatment should be initiated according to the patient's clinical signs and symptoms. A prolonged period of observation and treatment for these symptoms may be necessary, taking into account the long half-life of OZEMPIC® of approximately 1 week.

More detailed information is available upon request.

For information about OZEMPIC® contact: Novo Nordisk Inc., 800 Scudders Mill Road, Plainsboro, NJ 08536, 1-888-693-6742

Date of Issue: December 2017

Version: 1

Manufactured by: Novo Nordisk A/S, DK-2880 Bagsvaerd, Denmark

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PATENT INFORMATION:

http://novonordisk-us.com/patients/products/product-patents.html

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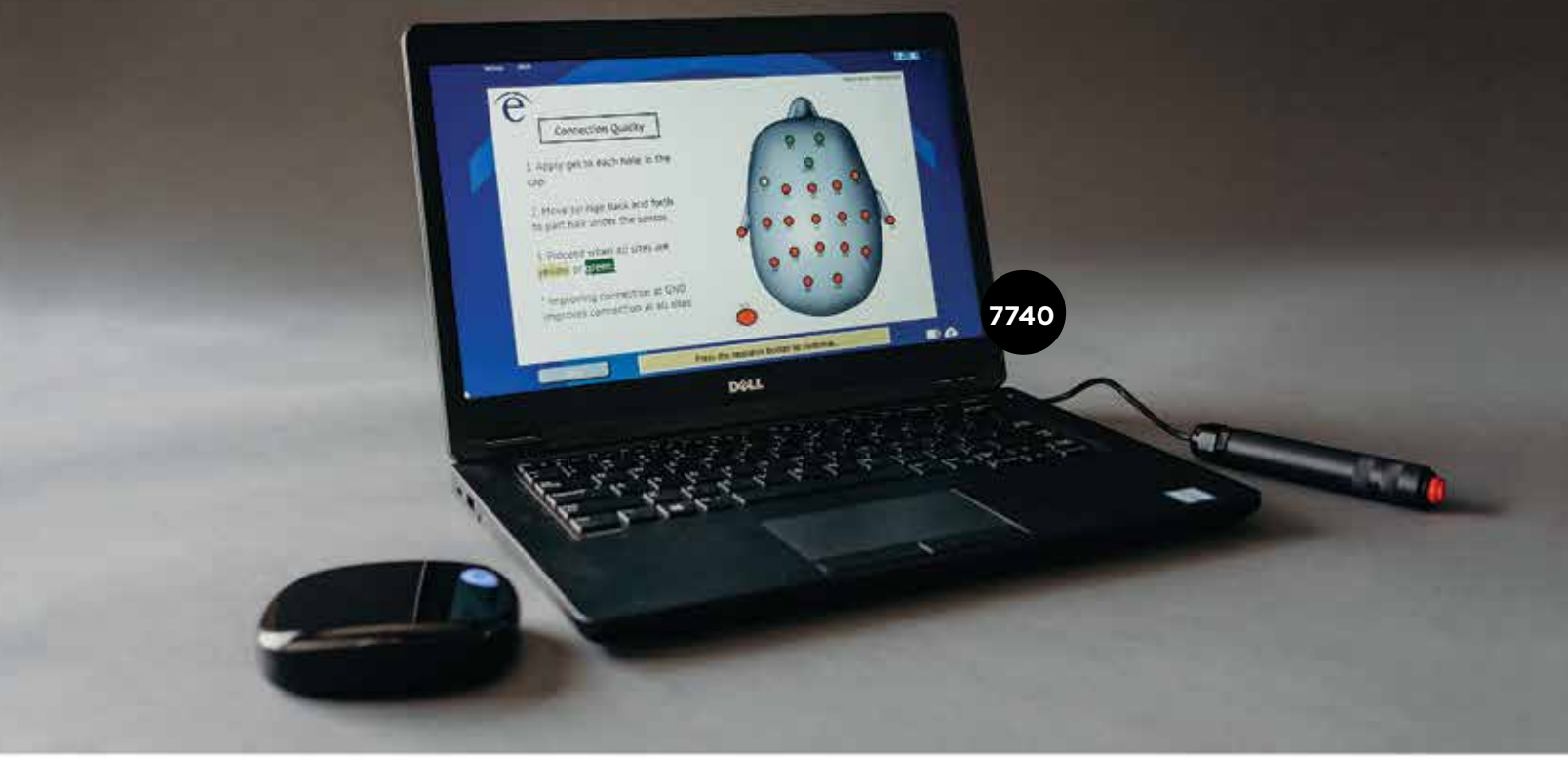
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[1]2019 NATIONAL AVERAGE MEDICARE PHYSICIAN FEE SCHEDULE, NON FACILITY SETTING https://www.cms.gov/apps/physician-fee-schedule/overview.aspx
Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019 Final Rule.

[2]Boise L, et al. Am J Alzheimers Dis 1999;14:20-26.



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