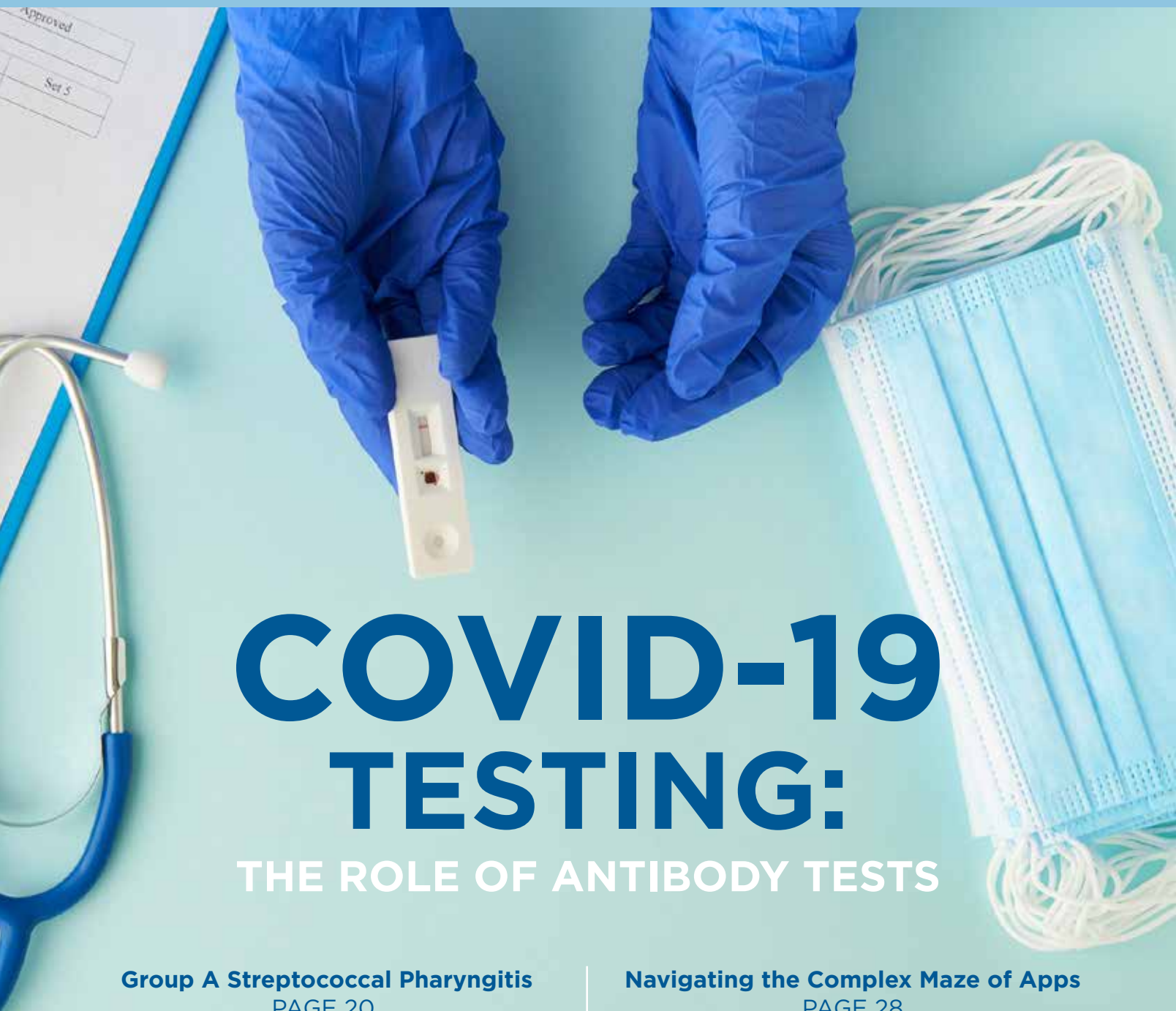
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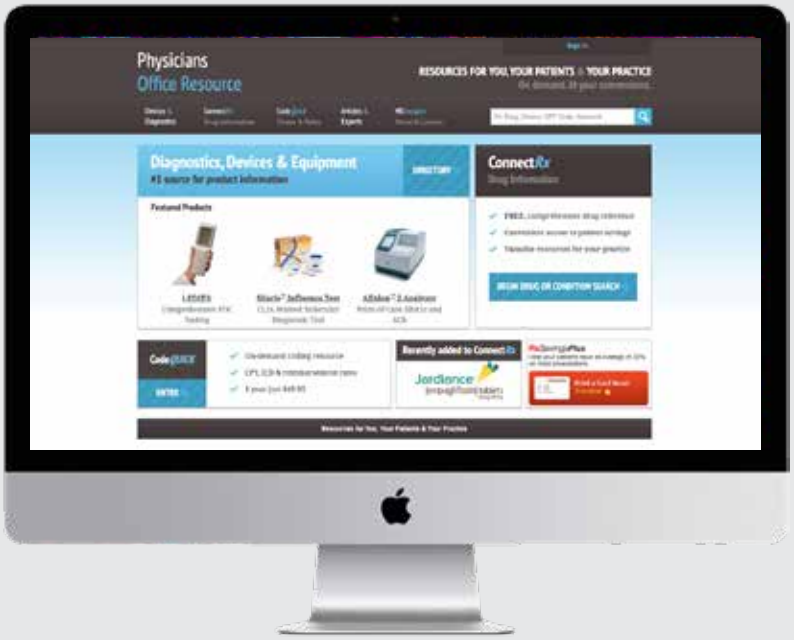


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Reference: 1. Wieman TJ, Smiell JM, Su Y. Efficacy and safety of a topical gel formulation of recombinant human platelet-derived growth factor-BB (becaplermin) in patients with chronic neuropathic diabetic ulcers. A phase III randomized placebo-controlled double-blind study. Diabetes Care. 1998;21:822-827.

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10

COVID-19 TESTING:
THE ROLE OF ANTIBODY TESTS

Testing for COVID-19 remains a tricky thing. Even though most states have expanded their testing abilities to screen thousands of additional patients, health departments are warning that turnaround times for results have slowed. These testing facilities are utilizing molecular testing via PCR, which has the ability to detect the presence of genetic material from the virus. In the month of May test result turn around times averaged one to two days. In the month of June turn around time increased to two to three days.

20 **Group A Streptococcal Pharyngitis Testing**

Strep tests are used to determine if a person with a sore throat (pharyngitis) has strep throat, an infection of the throat and tonsils caused by the bacteria Streptococcus pyogenes, also called Group A Streptococcus (GAS), or if the sore throat is caused by a virus. The majority of sore throats (70%-85%)1 are actually viral in nature, and will resolve without treatment within a few days.

28 **Navigating the Complex Maze of Apps**

There is no question that the COVID pandemic has forever changed healthcare. Telemedicine, virtual patient consults and increased use of remote patient monitoring are just some of the byproducts of the pandemic. As welcome as some of these changes are they have also brought with them some new concerns. This is particularly true in the area of chronic disease management.

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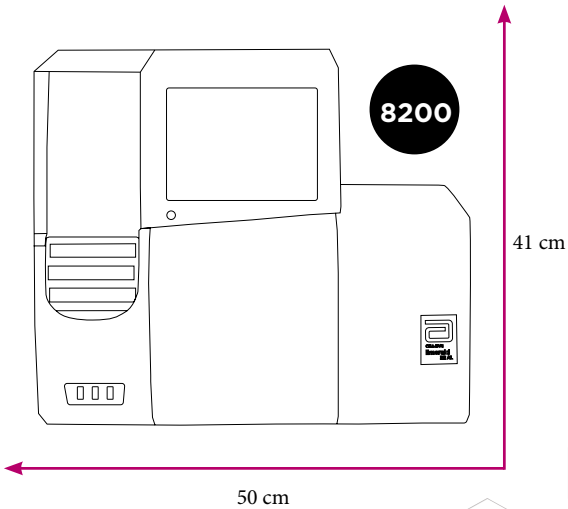
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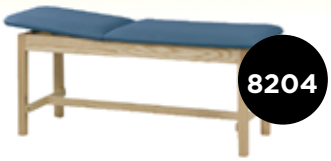
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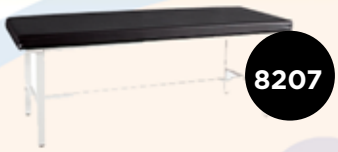
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COVID-19 TESTING:

The Role of Antibody Tests

BY AARON MEDARIS, PUBLISHER, PHYSICIANS OFFICE RESOURCE

Testing will only increase for the foreseeable future. Please be ready to help your patients and aid in the fight against this pandemic with the aide of COVID-19 antibody tests.

—

The Testing Dilemma

Testing for COVID-19 remains a tricky thing. Even though most states have expanded their testing abilities to screen thousands of additional patients, health departments are warning that turnaround times for results have slowed. These testing facilities are utilizing molecular testing via PCR, which has the ability to detect the presence of genetic material from the virus. In the month of May test result turn around times averaged one to two days. In the month of June turn around time increased to two to three days. Today test results take an average of four to six days. As for why the dramatic increase in turnaround times, diagnostic companies such as Quest are citing "unprecedented demands" especially in the South where COVID-19 cases are spiking.

Waiting six days for COVID-19 test results not only delays proper care and treatment but can also have a significant impact on the containment of the virus. As we know, the virus presents itself in a variety of different ways in different people. While waiting up to six days for test results, those experiencing only mild symptoms or who had a short bout of symptoms may decide for themselves that they don't or did not have it and thus unknowingly spread the virus to others.

Antibody Tests in the fight against COVID-19

COVID-19 molecular PCR tests detect the presence of genetic material from the virus – meaning that the patient is currently infected with the virus. This type of testing represents the gold standard in the fight against COVID-19 and the test that most facilities and health departments are utilizing. However, there are other tests available, but they differ in methodology and in results. Antibody testing is one of those tests available, it can determine if an individual currently has COVID-19 or has recovered from COVID-19.

IgM Antibody Tests

There are two antibody tests to be aware of, IgM and IgG. IgM is found mainly in the blood and lymph fluid and is the first antibody that body makes when fighting a new infection. An IgM antibody test for COVID-19 is hence a blood test which will detect the IgM antibody for COVID-19. One thing to be aware of is that at the start of an infection the body may not have had sufficient time to produce IgM antibodies. Therefore, these tests may not yield appropriate results if the test has been administered too early. Additionally, those who may be asymptomatic may not exhibit a sufficient immune response to produce a positive test. Even with these limitations one great advantage that IgM antibody tests have is their ability to produce results within 10-20 minutes.

IgG Antibody Tests

IgG antibody tests test for IgG antibodies in blood and other bodily fluids. IgG antibodies are the most common antibodies in our bodies, but often take 7 to 10 days to develop. When testing for COVID-19, IgG antibody only tests should only be administered to those who feel like they have previously had COVID-19 and recovered. Luckily most COIVD-19 antibody tests on the market test for both IgM and IgG antibodies. Thereby providing a clearer picture of the patient and their battle against COVID-19.

How Antibody Tests Can Help

Despite only being able to test for the antibody and not for the infection itself, IgM/IgG antibody tests can still be an important tool in the fight against COVID-19.

1. Antibody tests are rapid, many producing results in under 20 minutes. Which could greatly help with the increased testing demand which we are currently facing.

2. Antibody tests are widely available to medical facilities across the US.

3. Antibody tests can help us better understand the impact of the COVID-19 pandemic. Everything from giving us a better understanding of how long these antibodies remain in our bodies, identifying potential plasma donors, and tracking the virus in communities.

Testing will only increase for the foreseeable future. Please be ready to help your patients and aid in the fight against this pandemic with the aide of COVID-19 antibody tests.



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CGRP: calcitonin gene-related peptide; **SQ:** subcutaneous.

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 the Brief Summary of the Prescribing Information on the adjacent page.

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

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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.

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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 and gestational hypertension 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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This Brief Summary is based on the full Prescribing Information for AJOVY AJO-004.

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FEATURE

Group A Streptococcal Pharyngitis

Testing Guidelines & Procedural Limitations

BY IRWIN Z. ROTHENBERG, MBA, MS, CLS(ASCP),
TECHNICAL WRITER /QUALITY ADVISOR, COLA RESOURCES, INC.

Introduction

Strep tests are used to determine if a person with a sore throat (pharyngitis) has strep throat, an infection of the throat and tonsils caused by the bacteria Streptococcus pyogenes, also called Group A Streptococcus (GAS), or if the sore throat is caused by a virus. The majority of sore throats (70%-85%)[2] are actually viral in nature, and will resolve without treatment within a few days.

However, it is important to determine when sore throats are caused by GAS, since this is the most common bacterial cause of acute pharyngitis, responsible for 5%–15% of sore throat visits in adults and 20%–30% in children. It is most common in children ages 5 to 15 years old (over 50 % of the cases occur within this age bracket[3]); it is very contagious; and needs to be identified as soon as possible, and treated with antibiotics[4].

Accurate diagnosis of streptococcal pharyngitis followed by appropriate antimicrobial therapy is important for the prevention of acute rheumatic fever; for the prevention of suppurative complications (e.g. peritonsillar abscess, cervical lymphadenitis, mastoiditis, and, possibly, other invasive infections); to improve clinical symptoms and signs; for the rapid decrease in contagiousness; for the reduction in transmission of GAS to family members, classmates, and other close contacts of the patient; to allow for the rapid resumption of usual activities; and for the minimization of potential adverse effects of inappropriate antimicrobial therapy[5].

Fortunately, most streptococcal infections are now routinely diagnosed and treated through rapid strep testing, these complications are rare in the United States, but they do still occur[6].

Establishing the Diagnosis of GAS Pharyngitis7

1. Swabbing the throat and testing for GAS pharyngitis by rapid strep test and/or throat culture should be performed because clinical features alone do not reliably discriminate between GAS and viral pharyngitis except when overt viral features like runny nose, cough, oral ulceration, and/or hoarseness are present. In children and adolescents, negative rapid strep tests should be backed up by a throat culture; however, positive rapid strep tests do not necessitate a back-up culture because they are highly specific.

2. The routine use of back-up throat cultures for those with a negative rapid strep test is not generally recommended for adults, because of the low incidence of GAS pharyngitis, and because the risk of subsequent acute rheumatic fever is exceptionally low. Physicians who wish to ensure they are achieving maximal sensitivity in diagnosis may (of course) continue to use conventional throat culture or back up negative rapid strep tests with a culture.

3. Anti-streptococcal antibody titers are not recommended in the routine diagnosis of acute pharyngitis as they reflect past but not current events.



Who Should Undergo Testing for GAS Pharyngitis?[8]

Testing for GAS pharyngitis usually is not recommended for children or adults with acute pharyngitis with clinical and epidemiological features that strongly suggest a viral basis (e.g, cough, runny nose, hoarseness, and oral ulceration).

Diagnostic studies for GAS pharyngitis are not indicated for children under three years old because acute rheumatic fever is rare in children under three years old, and the incidence of streptococcal pharyngitis and the classic presentation of streptococcal pharyngitis are uncommon in this age group. Selected children under three years old who have other risk factors, such as an older sibling with GAS infection, may be considered for testing

Follow-up post treatment throat cultures or rapid strep testing are not recommended routinely but may be considered in special circumstances

Diagnostic testing or empiric treatment of asymptomatic household contacts of patients with acute streptococcal pharyngitis is not routinely recommended

If the results of the rapid strep test are positive, further testing is not necessary, and treatment can be started immediately.

Testing Guidelines

l. The Rapid Strep Test (RST)

Description[9]

A major disadvantage of throat cultures is the delay (overnight or longer) in obtaining results. RSTs have been developed for the identification of GAS pharyngitis directly from throat swabs, with shorter turnaround time. Rapid identification and treatment of patients with GAS pharyngitis can reduce the risk of spread, allowing the patient to return to school or work sooner, and can reduce the acute associated morbidity. The use of RSTs for certain populations (e.g, patients in emergency departments) was reported to significantly increase the number of patients appropriately treated for streptococcal pharyngitis, compared with traditional throat cultures.

RSTs currently available are highly specific (approximately 95%) when compared with blood agar plate cultures. False-positive test results are highly unusual, and therefore therapeutic decisions can be made with confidence on the basis of a positive test result. Unfortunately, the sensitivity of most of these tests is 70%–90%, compared with blood agar plate culture.

The first RSTs used latex agglutination methods, were relatively insensitive, and had unclear end points. Newer tests based on

enzyme immunoassay techniques offer increased sensitivity and a more sharply defined end point.

The practitioner should be aware that some of these rapid strep tests are not waived, and therefore, require proper certification or accreditation of the physician's laboratory. Neither conventional throat culture nor RSTs accurately differentiate acutely infected persons from asymptomatic streptococcal carriers with viral pharyngitis. Nevertheless, they allow physicians to withhold antibiotics from the great majority of patients with sore throats for whom results of culture or RST are negative. This is of extreme importance, because nationally up to 70% of patients with sore throats seen in primary care settings receive prescriptions for antimicrobials, while only 20%–30% are likely to have GAS pharyngitis.

Since the sensitivities of the various RSTs are <90% in most studied populations of children and adolescents, and because the proportion of acute pharyngitis due to GAS in children and adolescents is sufficiently high (20%–30%), a negative RADT should be accompanied by a follow-up or back-up throat culture in children and adolescents, while this is not necessary in adults under usual circumstances, as noted above.

Procedure[10]

Obtaining a specimen is the same whether your doctor will do a throat culture or rapid test for strep. A cotton swab (similar to a Q-tip) is quickly rubbed over both tonsils as well as the back wall of the mouth (the posterior pharynx). It is important to avoid contact with other structures inside the mouth such as the tongue or cheeks. The swab is then placed in a specialized container and the rapid test performed. Many people find that obtaining the swab produces a gagging sensation. However, since the entire swabbing process lasts less than five seconds this inconvenience is minimal.

Limitations[11]

There are several manufactures of rapid strep tests. Each manufacturer has designed their test to respond only to the presence of the particular streptococcal bacteria (Group A) responsible for strep throat. Other bacteria which are less much less likely to cause sore throats are not identified by the rapid strep test.

The test will not detect viral causes of sore throat.

A positive test response occurs when a reaction occurs between a protein on the surface of strep bacteria and chemicals in the test materials. Either living or dead strep bacteria will produce a positive reaction. A positive culture requires antibiotics, nevertheless.

Most rapid strep tests have a sensitivity of 90%, meaning that the test will be positive in 90 of 100 patients who are documented to have strep throat via throat culture obtained at the same time. Since 10 of 100 patients with strep throat will be missed using a rapid strep test, all negative swab specimens should be sent for culture to confirm the absence of strep bacteria.

The rapid strep test has a 98% specificity. This means that 98 of 100 positive tests correctly indicate the presence specifically of Group A streptococcus bacteria; 2 of 100 positive results are «false positives» - indicative of similarities between various surface proteins found on strep bacteria and other non-strep bacteria found in the mouth.

ll. The Throat Culture

Culture of a throat swab on a sheep-blood agar plate has historically been the standard for the documentation of the presence of GAS pharyngitis in the upper respiratory tract and for the confirmation of the clinical diagnosis of acute streptococcal pharyngitis. If performed correctly, culture of a single throat swab on a blood agar plate is 90%–95% sensitive for detection of GAS pharyngitis. A major disadvantage of throat cultures is the delay (overnight or longer) in obtaining results. This spurred the development and adoption of rapid strep testing directly from throat swabs, with shorter turnaround time[12].

Limitations[13]

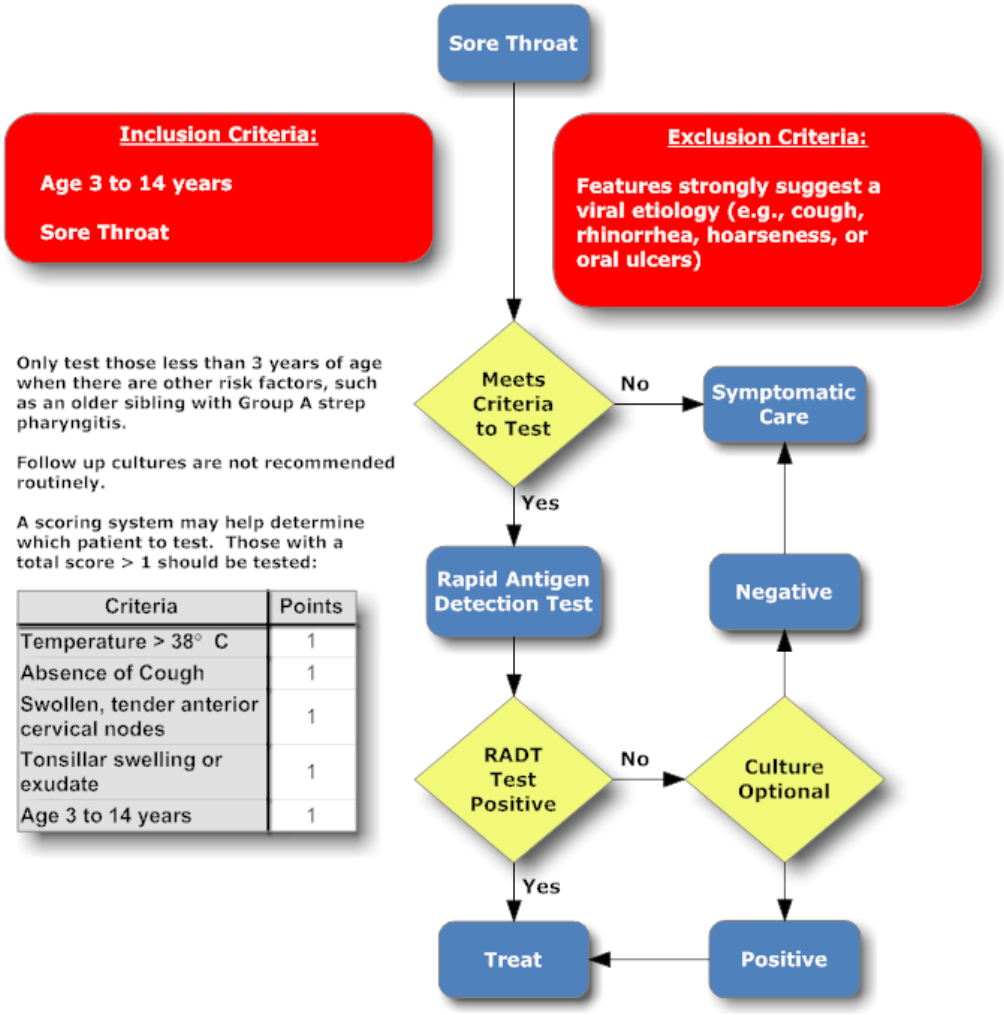
Several variables affect the accuracy of throat culture results. For example, the manner in which the swab is obtained has an important impact on the yield of streptococci. Throat swab specimens should be obtained from the surface of either tonsils (or tonsillar fossae) and the posterior pharyngeal wall. Other areas of the oral pharynx and mouth are not acceptable sites. Healthcare professionals who try to obtain a throat swab from an uncooperative child without immobilizing the neck may obtain a specimen that is neither adequate nor representative. In addition, false-negative results may be obtained if the patient has received an antibiotic shortly before the throat swab is obtained.

Another variable that can affect the throat culture result is the duration of incubation. Once plated, a culture should be incubated at 35°C–37°C for 18–24 hours before reading. Additional incubation overnight at room temperature may identify a number of additional positive throat culture results. Thus, although initial therapeutic decisions may be made on the basis of overnight culture, it is advisable to reexamine plates at 48 hours that yield negative results at 24 hours.

The clinical significance of the number of GAS colonies on the throat culture plate is problematic. Although patients with true acute GAS pharyngitis are likely to have more strongly positive cultures than patients who are streptococcal carriers (i.e, individuals with chronic GAS colonization of the pharynx), there is too much overlap in this regard to permit accurate differentiation on this basis alone.

Summary of The Testing Protocol for Group A Streptococcal Pharyngitis[14]

UW Medicine General Pediatric Division
Management of Sore Throat



Only test those less than 3 years of age when there are other risk factors, such as an older sibling with Group A strep pharyngitis.

Follow up cultures are not recommended routinely.

A scoring system may help determine which patient to test. Those with a total score > 1 should be tested:

Criteria	Points
Temperature > 38° C	1
Absence of Cough	1
Swollen, tender anterior cervical nodes	1
Tonsillar swelling or exudate	1
Age 3 to 14 years	1

Treatment can be a single dose of IM benzathine G pencillin, or
10 days of oral penicillin, amoxicillin, cephalexin, or
5 days of azithromycin

ENDNOTES

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NAVIGATING THE COMPLEX MAZE OF APPS

BY DAVID KLIFF OF THE DIABETIC INVESTOR

There is no question that the COVID pandemic has forever changed healthcare. Telemedicine, virtual patient consults and increased use of remote patient monitoring are just some of the byproducts of the pandemic. As welcome as some of these changes are they have also brought with them some new concerns. This is particularly true in the area of chronic disease management. Physicians have always been acutely aware that their patients with chronic diseases such as diabetes have the additional burden of monitoring their condition.

In the old days before all the gizmos a patient used communicated with their smartphone, patients with diabetes would record their glucose readings in an old-fashioned logbook. There were no such thing as connected insulin pens or continuous glucose monitoring systems which not only collected data but shared this data with an app, which in turn then could be shared with their physician.

This new world on interconnected devices brings with it some promise and some peril. In theory all this connectivity can help the patient more effectively manage their diabetes. Using connectivity the patient can easily share all this information with their physician who in turn can then better advise the patient. Thanks to COVID physicians can now more easily bill for these virtual consultations. Still there is little uniformity in how all this data is presented or transmitted. Nor are there any standards or restrictions on how these apps communicate with the user.

The last thing any physician needs is for an app to be telling the patient one thing, when they are telling the patient something else. To our knowledge there is just one diabetes app which has received FDA approval, Diabetes Manager by WellDoc. This basically means when it comes to the plethora of diabetes apps choosing which one is best for your patients with diabetes is pretty much like rolling the dice on a crap table.

To help navigate this complex maze here are some simple tips that will help enhance the physician patient relationship.

Is an app needed in the first place?

This may seem like a dumb question but in reality there are some patients who don't need or don't want to deal with all this way cool whiz bang technology. Just by way of example a Type 2 patient on oral medication(s) alone may see an app as overburdensome. Sure it would be nice to know how their glucose levels are trending but any changes to their therapy regimen are more likely to be based on a multiplicity of factors including their most recent HbA1c.

What information is needed?

To a great extent this question is also answered by the patient's therapy regimen. Is the patient following intensive insulin therapy? Or are they using insulin plus orals? Keep in mind that glucose data is not the lone data point that can be collected by an app. Given the importance of food intake there are a host of apps which allow the patient to record meal intake. There are also several apps which record the patient's weight, blood glucose monitors and CGM's aren't the only devices which send data to apps.

Is data all that's needed or should coaching be included?

One thing most of these apps are very good at is data collection.

"This new world on interconnected devices brings with it some promise and some peril."

However there are an equal number which go beyond mere data collection and apply analytics to all this data. These analytical apps can provide valuable insight into how the patient is managing their diabetes.

Recently a bundle of apps have gone well beyond data collection combined with data analytics. These newer apps have entered the world of patient coaching offering the patient tips on how they can more effectively manage their diabetes. Using text messaging these apps can send these tips directly to the patient bypassing any physician input or oversight.

Is this information safe?

It would be foolish in today's world to ignore the security of a patient's personal health information and these apps are no different. Several studies have noted that cybersecurity or the fear of information being hacked is the number one concern for patients. Given that there are no universal standards which govern how these apps should protect all this data this is a very legitimate concern. While we would not go as far and state that it's the wild west out in diabetes app land without any uniform standards combined with the complexity of factors involved we don't see this concern going away.

What's the goal?

Again this seems like a stupid question as the default response is better patient outcomes. Yet the real consideration is will use of these apps achieve this goal. Here too there are numerous studies which unfortunately draw different conclusions. Some studies have concluded that these apps help strengthen the doctor patient relationship providing more productive interactions. Others however have concluded that as helpful as all this information can be this avalanche of information creates more questions.

There is no question that apps are here to stay and will see greater usage. The real yet unanswered question is will use of these apps lead to better outcomes. Will patients and their physicians embrace this technology, or will they become another diabetes tool that goes unused?

On balance we see more positives than negatives however we continue to believe that it's not about the toys in the toy chest. That it's all about getting the patient to play with the toys.



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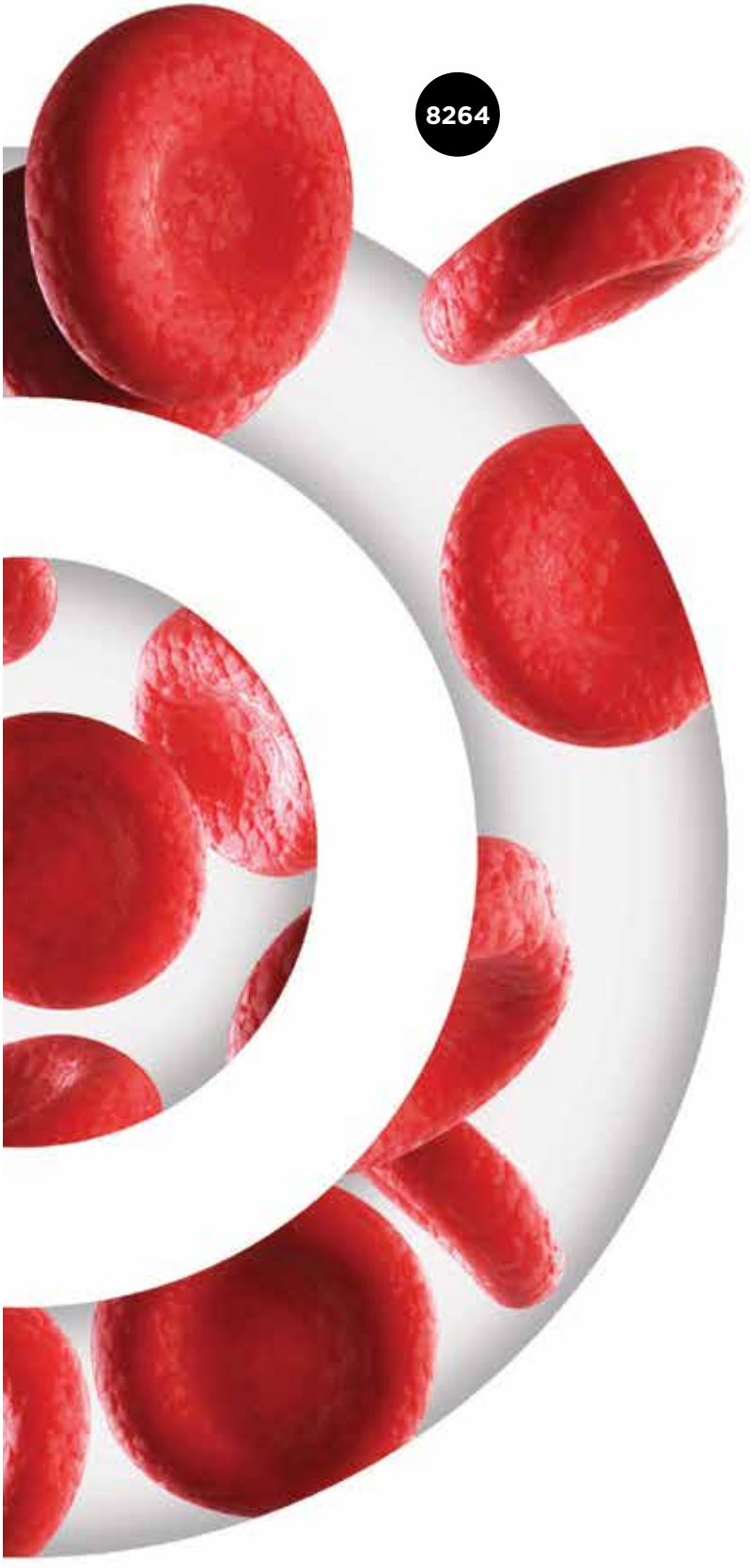
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For adult patients with type 2 diabetes, treated with diet and exercise

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

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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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semaglutide injection 0.5mg|1mg



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8270



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8271

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References:
1. BD Veritor System for Rapid Detection of Flu A+B, CLIA-waived 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.

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