OPTIMAL SCRIPTS

Drug Education Message

Medication Description

- Semaglutide 0.5 mg / Vitamin B6 Pyridoxine HCL) 10 mg. Tablet is white in color.
- Semaglutide 1.0 mg / Vitamin B6 (Pyridoxine HCL) 10 mg. Tablet is white in color.
- Semaglutide 1.5 mg / Vitamin B6 (Pyridoxine HCL) 10 mg. Tablet is white in color.

Pyridoxine HCL (Vitamin B6)

Vitamin B6 is needed for the proper function of sugars, fats, and proteins in the body. It's also necessary for the development of the brain, nerves, skin, and many other parts of the body.

Semaglutide

Pronunciation: (sem a GLOO tide)
What is this drug used for?

- Semaglutide is the active ingredient that has helped thousands of people achieve and maintain weight loss when combined with diet and exercise. It works by boosting insulin production, reducing glucagon secretion, and targeting the areas of the brain that control appetite and food intake.
- It can also be used to manage blood sugar in people with type 2 diabetes.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances: Tell your doctor about the allergy and the symptoms you experienced. Additionally, inform your doctor:
- If you ever had pancreatitis
- If you have or have ever had depression or thoughts of suicide
- If you are taking another drug that has the same drug in it
- If you are using another drug like this one (If you are not sure, ask your doctor or pharmacist.)
- If you have type 1 diabetes (Do not use this drug to treat type 1 diabetes.)

  This is not a complete list of all drugs or health conditions that interact with this drug. Tell your doctor and pharmacist about all of your drugs (prescription and OTC, natural products, and vitamins) and health conditions. You must confirm that it is safe for you to take this drug along with your current drugs and existing health conditions. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while taking this drug?

- Tell all of your healthcare providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Follow the diet and workout plan recommended by your doctor.
- Have blood work done as recommended by the doctor. Talk with your doctor about any side effects that may occur. You may also report side effects to the FDA at 1-800-332-1088.
- Talk with your doctor before consuming alcohol.
- Kidney problems are possible. Sometimes, these may need to be treated in the hospital or with dialysis.
- If you cannot drink liquids by mouth or if you have upset stomach, throwing up, or diarrhea that does not go away; you may be at risk of dehydration. Contact your doctor right away for guidance. Dehydration may lead to low blood pressure, or to new or worse kidney problems.
- If you plan on becoming pregnant, talk with your doctor first. You may need to stop taking this drug at least 2 months before getting pregnant.
- Wear a medical alert ID (identification).
- Check your blood sugar as recommended by your doctor.
- Do not drive if your blood sugar is low. There is a greater chance of an accident.
- People taking this drug along with other drugs for diabetes may have an increased risk of low blood sugar. Very low blood sugar can lead to seizures, passing out, long-term brain damage, and sometimes death. Talk with your doctor before using this medication along with other drugs for diabetes.
- It may be harder to control blood sugar during times of physical stress such as fever, infection, injury, or surgery. A change in physical activity, exercise, or diet may also affect blood sugar.
- Tell your doctor if you are pregnant, plan on getting pregnant, or are breastfeeding. You will need to discuss the benefits and risks to you and your baby.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have severe and sometimes potentially deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a severe side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat
- Signs of kidney problems like the inability to pass urine, changes in how much urine is passed, blood in the urine, or significant weight gain
- Signs of gallbladder problems like pain in the upper right belly area, right shoulder area, or between the shoulder blades; changes in stools; dark urine or yellow skin or eyes; or fever with chills
- Severe dizziness or passing out
- Rapid heartbeat
- Changes in vision
- Low blood sugar can happen. The risk of low blood sugar may increase when this drug is used along with other drugs for diabetes. Signs may include dizziness, headache, feeling sleepy or weak, shaking, fast heartbeat, confusion, hunger, or sweating. Call your doctor right away if you have any of these signs. Follow your doctor's instructions for managing low blood sugar. This may include taking glucose tablets, liquid glucose, or fruit juice.
- Severe and sometimes deadly pancreas problems (pancreatitis) have happened with this drug. Call your doctor right away if you have severe stomach pain, severe back pain, or severe upset stomach or vomiting.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects are troublesome or do not go away:

- Constipation, diarrhea, stomach pain, upset stomach, or vomiting
- Decreased appetite

These are not all of the side effects that may occur. Call your doctor for further medical advice and with any questions you may have about side effects.

You may report side effects to the FDA at 1-800-332-1088. You may also report side effects at http://www.fda.gov/medwatch.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- Take at least 30 minutes before the first food, drink, or other drugs of the day.
- Take with plain water only. Do not take with more than 4 ounces (120 mL) of water.
- Rapid Dissolve Tables - This type of tablet is designed to rapidly dissolve in the mouth and/or under the tongue. Partially chewing tablet and allowing it to disintegrate orally is allowed.
- Keep taking this drug as you have been told by your doctor or other healthcare provider, even if you feel well.

What do I do if I miss a dose?

- Skip the missed dose and then return to your normal dosage schedule.
- Do not take 2 doses at the same time; do not take extra doses.

How do I store and/or dispose of this drug?

- Store in the original container at room temperature.
- Store in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Safely dispose of unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to dispose of drugs. There may be drug take-back programs in your area.

Optimal Scripts:

Your Trusted Pharmaceutical Partner

Sales Guide, Facilities, Licensures, and Certifications

About Optimal Scripts

- Optimal Scripts is a leading pharmaceutical brand committed to quality, safety, and innovation.
- Our facilities are fully automated, adhering to CGMP (Current Good Manufacturing Practices) standards.
- We are FDA-registered, ensuring compliance with rigorous regulatory requirements.

Our Facilities

- Optimal Scripts operates multiple 503A and 503B facilities in the USA.
- These facilities are equipped with state-of-the-art technology to produce high-quality pharmaceutical products.

Integrated Testing Labs

- Optimal Scripts is committed to quality. Our facilities have integrated testing labs for quality assurance.
- Our labs are CLIA (Clinical Laboratory Improvement Amendments)- and COLA (Commission on Office Laboratory Accreditation)-certified.
- Our labs conduct rigorous testing for safety and efficacy of our products.

Direct API Sourcing

- We source APIs (Active Pharmaceutical Ingredients) directly from originators.
- This promotes the highest qualityand traceability of our raw materials.

LegitScript-Certified

- Optimal Scripts is LegitScript-certified, assuring patients and healthcare providers of our legitimacy and ethical practices.

Licensure

- Optimal Scripts holds multiple FDA (Food and Drug Administration) and DEA (Drug Enforcement Administration) licenses.
- These licenses demonstrate our commitment to compliance and safety.

Optimal Scripts: A Comparison of 503A and 503B Compounding Pharmacies

Compounding Pharmacies

The Optimal Scripts brand is comprised of several 503A and 503B compounding pharmacies. Each plays a specific role in our manufacturing, logistical, and sales processes. Understanding the differences between the two will empower the sales force to explain why Optimal Scripts, made in America, is simply the best choice on the market.

Designations
503A Compound Pharmacies
503B Outsourcing Facilities

Regulatory Oversight
503A: Primarily regulated by state boards of pharmacy
503B: Regulated by the U.S. Food and Drug Administration (FDA)

Bulk Compounding
503A: Limited to small-scale compounding for individual patient prescriptions
503B: Permitted to produce large batches of compounded medications not for specific patient prescriptions

Quality Standards
503A: Subject to USP <795> and <797> standards for compounding practices
503B: Required to adhere to Current Good Manufacturing Practices (CGMP) standards

Drug Testing
503A: May perform in-house testing of compounded medications
503B: Required to conduct rigorous testing and quality assurance protocols

Labeling
503A: Must include patient-specific information and directions for use
503B: Labels must comply with FDA regulations for commercial drug products

Prescription Requirements
503A: Requires patient-specific prescriptions for each compounded medication
503B: Can compound medications without patient-specific prescriptions for office use

Optimal Scripts: How We Developed Our Generic Drug

The process for a generic drug to enter the market in the United States involves several steps regulated by the U.S. FDA. Here's an overview of the process that approved Optimal Script's generic semaglutide:

1. Submission of Abbreviated New Drug Application (ANDA):

The manufacturer of the generic drug submits an Abbreviated New Drug Application (ANDA) to the FDA. This application includes data demonstrating the drug's bioequivalence to the brand-name drug, as well as information on its safety, efficacy, manufacturing process, and labeling.

2. Review and Evaluation by the FDA:

The FDA reviews the ANDA to ensure that the generic drug meets the same quality, safety, and efficacy standards as the brand-name drug. This involves assessing the bioequivalence of the generic drug to the brand-name drug, as well as evaluating its manufacturing process and labeling.

3. Approval of the ANDA:

If the FDA determines that the generic drug is bioequivalent to the brand-name drug and meets all other regulatory requirements, it approves the ANDA. This allows the manufacturer to market and distribute the generic drug in the United States.

4. Patent Challenges:

Before granting final approval, the FDA may need to address any patent challenges or exclusivity rights associated with the brand-name drug. This can involve litigation between the generic manufacturer and the brand-name manufacturer to resolve patent disputes.

5. Post-Market Monitoring:

After the generic drug is approved and enters the market, the FDA continues to monitor its safety and efficacy through post-market surveillance programs. This helps ensure that any potential safety concerns are promptly identified and addressed. Overall, the process for a generic drug to enter the market in the U.S. involves rigorous evaluation by the FDA to ensure that it is safe, effective, and of high quality. This helps provide patients with access to affordable medications while maintaining stringent regulatory standards.