#### Chad's Wellness

### chadswellness@gmail.com

405-821-4398

## **Important Safety Information**

Do not share your Semaglutide even if the needle has been changed. You may give other people a serious infection, or get a serious infection from them.

What is the most important information I should know about Semaglutide®?

Semaglutide® may cause serious side effects, including:

- Possible thyroid tumors, including cancer. Tell your health care provider if you get a lump or swelling in your neck, hoarseness, trouble swallowing, or shortness of breath. These may be symptoms of thyroid cancer. In studies with rodents, Semaglutide® and medicines that work like Semaglutide® caused thyroid tumors, including thyroid cancer. It is not known if Semaglutide® will cause thyroid tumors or a type of thyroid cancer called medullary thyroid carcinoma (MTC) in people.
- Do not use Semaglutide® if you or any of your family have ever had MTC, or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

# Do not use Semaglutide if:

- you or any of your family have ever had MTC or if you have MEN 2.
- you are allergic to semaglutide or any of the ingredients in Semaglutide®.
- Before using Semaglutide®, tell your health care provider if you have any other medical conditions, including if you:
- have or have had problems with your pancreas or kidneys.
- have a history of diabetic retinopathy.
- are pregnant or breastfeeding or plan to become pregnant or breastfeed. It is not known if Semaglutide® will harm your unborn baby or passes into your breast milk. You should stop using Semaglutide® 2 months before you plan to become pregnant.

**Tell your health care provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, herbal supplements, and other medicines to treat diabetes, including insulin or sulfonylureas.

#### What are the possible side effects of Semaglutide®?

Semaglutide may cause serious side effects, including:

- **inflammation of your pancreas (pancreatitis).** Stop using Ozempic<sup>®</sup> and call your health care provider right away if you have severe pain in your stomach area (abdomen) that will not go away, with or without vomiting. You may feel the pain from your abdomen to your back.
- **changes in vision.** Tell your health care provider if you have changes in vision during treatment with Semaglutide.
- low blood sugar (hypoglycemia). Your risk for getting low blood sugar may be higher if you use Semaglutide® with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin. Signs and symptoms of low blood sugar may include: dizziness or lightheadedness, blurred vision, anxiety, irritability or mood changes, sweating, slurred speech, hunger, confusion or drowsiness, shakiness, weakness, headache, fast heartbeat, and feeling jittery.
- kidney problems (kidney failure). In people who have kidney problems, diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration), which may cause kidney problems to get worse. It is important for you to drink fluids to help reduce your chance of dehydration.
- **serious allergic reactions.** Stop using Semaglutide® and get medical help right away if you have any symptoms of a serious allergic reaction, including swelling of your face, lips, tongue, or throat; problems breathing or swallowing; severe rash or itching; fainting or feeling dizzy; or very rapid heartbeat.
- **gallbladder problems.** Gallbladder problems have happened in some people who take Semaglutide. Tell your health care provider right away if you get symptoms which may include: pain in your upper stomach (abdomen), fever, yellowing of the skin or eyes (jaundice), or clay-colored stools.

The most common side effects of Semaglutide® may include nausea, vomiting, diarrhea, stomach (abdominal) pain, and constipation.

Commercial, brand-name medications don't always meet patients' needs, so a 503A compounding pharmacy creates individualized products to meet those needs. For example, if a patient is allergic to a dye or ingredient in a commercial drug, a compounding pharmacy can create the drug without that allergen so the patient can take the medication.

When utilizing a 503A compounding pharmacy, patients can trust that their prescriptions are tailored to their individual clinical needs, health journeys, and lifestyles.

### **Expanding Patient Access**

**503A** pharmacies compound medications for specific patients whose prescriptions are sent in by their healthcare provider. Empower Pharmacy works with thousands of providers to make sure patients have access to quality, affordable medications. We are licensed nationwide and can ship prescriptions directly to patients. <u>Get in touch with Empower Pharmacy</u> to find out more.

## **Regulating 503A Compounding Pharmacies**

Unlike a <u>503B outsourcing facility</u> that produces large-scale batches of medications for use in medical offices, a 503A facility produces patient-specific medications pursuant to a prescription.

It is required by state boards of pharmacy to adhere to the <u>United States Pharmacopeia</u> (USP) chapter <797>, <795>, <800> and other guidelines. USP develops standards around product integrity, safety, and purity in compounding.

**USP General Chapter <797>**: This is a set of guidelines for sterile compounding preparations. This type of compounding utilizes an aseptic technique, which happens in an environment where there are absolutely no bacteria, viruses, or other foreign microorganisms. The professionals who compound this way must wear sterile gloves, gowns, and masks, use sterile equipment, and must minimize the number of people in the environment. Products that are administered intravenously (IV) or intramuscularly (IM) are created in a sterile environment.

**USP General Chapter <795>**: This is a set of guidelines specifically for nonsterile compounding preparations. The standards are still high to ensure the quality and safety of products, but they are not as rigid as those for sterile compounding. Nonsterile products are often medications in powder, tablet, or capsule form, among others. Empower Pharmacy compounds both sterile and nonsterile products.

**USP <800>**: This set of guidelines applies to the handling of hazardous drugs in healthcare settings. It exists to make sure hazardous drugs are handled properly to make sure there is minimal risk of exposure to patients, providers, and healthcare workers.

# **Additional Oversight & Standards**

State boards of pharmacy regulate 503A compounding pharmacies, but compounding pharmacies are also subject to some oversight by state and federal agencies. The **DEA** has primary oversight of any controlled substances (i.e., testosterone) present in compounded products. The **FDA** has <u>published</u> <u>guidance</u> that applies to 503A compounding pharmacies. Empower Pharmacy is licensed nationwide, partners with licensed providers, and meets or exceeds industry standards.

I understand that this is a compounded medication and it has the same active ingredient as Ozempic but compounded with Vitamin B12. I also know and accept the risks that go along with taking this medication.

Signature	Date
Printed Name	<del></del>