

# SEMAGLUTIDE RISKS AND CONTRAINDICATIONS

In June of 2021 semaglutide was approved by the FDA for weight loss. In October of 2022, tirezepatide was given the "fast track" status by the U.S. Food and Drug Administration (FDA) to treat obesity. Both drugs are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus, neither is indicated for use in patients with type 1 diabetes mellitus.

## **DO NOT USE THESE DRUGS IF:**

You or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MC) or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). These drugs caused thyroid C-cell tumors in rats. It is unknown whether tirezepatide causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as the human relevance of tirzepatide-induced rodent thyroid C-cell tumors has not been determined • tirezepatide is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC and symptoms of thyroid tumors.

## **CONTRAINDICATIONS:**

Serious hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with both tirezepatide and semaglutide. There is also a risk of Thyroid C-cell Tumors, Hypoglycemia with Concomitant Use of Insulin Secretagogues or Insulin, Hypersensitivity Reactions, Acute Kidney Injury, Severe Gastrointestinal Disease, Diabetic Retinopathy Complications in Patients with a History of Diabetic Retinopathy, Acute Gallbladder Disease. Pancreatitis Has been reported in clinical trials. Discontinue promptly if pancreatitis is suspected. Do not restart if pancreatitis is confirmed.

## MOST COMMON ADVERSE REACTIONS:

Nausea, diarrhea, decreased appetite, vomiting, constipation, dyspepsia, and abdominal pain.

## **DRUG INTERACTIONS:**

Insulin, pregnancy complications with exposure to trizeptate, lactation, females using oral hormonal contraceptives to switch to a non-oral contraceptive method or add a barrier method of contraception for 4 weeks after initiation and 4 weeks after each dose escalation. Not recommended in patients less than 18 years of age. When initiating semaglutide consider reducing the dose of concomitantly administered insulin secretagogue (such as sulfonylureas) or insulin to reduce the risk of hypoglycemia. Semaglutide causes a delay of gastric emptying and has the potential to impact the absorption of concomitantly administered oral medications, so caution should be exercised.

## DOSAGE FORMS AND STRENGTHS FOR SEMAGLUTIDE

- Start at 0.25 mg once weekly. After 4 weeks, increase the dose to 0.5 mg once weekly.
- If additional glycemic control is needed, increase the dose to 1 mg once weekly after at least 4 weeks on the 0.5 mg
  dose.
- If additional glycemic control is needed, increase the dose to 2 mg once weekly after at least 4 weeks on the 1 mg dose. Administer once weekly at any time of day, with or without meals.
- If a dose is missed, administer within 5 days of missed dose.
   Inject subcutaneously in the abdomen, thigh, or upper arm

# 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 what signs you have.
- If you have ever had pancreatitis or problems with your kidneys, or severe problems with your stomach, such as slowed emptying of your stomach or problems digesting food.
- If you have or have ever had depression or thoughts of suicide.
- If you are using another drug like this one. If you are not sure, ask your doctor or pharmacist.
- Talk to your healthcare provider about low blood sugar and managing it.
- If you take birth control pills by mouth, talk to your healthcare provider before you use this drug because birth control pills may not work as well. Your healthcare provider may recommend another type of birth control for 4 weeks after you start your injection and 4 weeks after each increase in your dose of your injection.

- Are you pregnant, plan to become pregnant, breastfeeding, or plan to breastfeed? It is unknown if these medications will harm
  your unborn baby or pass into your breast milk.
- Do you take other diabetes medicines, such as insulin or sulfonylureas?
- Do you have a history of diabetic retinopathy?
- Tell your doctor and pharmacist about all your drugs (prescription or OTC, natural products, vitamins) and health conditions. You must check to make sure that it is safe for you to take this drug with all your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

## **HOW SHOULD I USE?**

- Read the Instructions for Use and use exactly as your healthcare provider tells you to.
- Tell all your healthcare providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Follow the diet and exercise plan that your doctor told you about.
- Have blood work checked as you have been told by the Do not mix insulin and tirezepatide or semaglutide together in the same injection.
- You may inject tirezepatide or semaglutide and insulin in the same body area (such as your stomach area), but not right next to
  each other.
- Change (rotate) your injection site with each weekly injection. Do not use the same site for each injection.
- If you take too much, call your healthcare provider.
- Talk with your doctor before you drink alcohol.
- Do not share used syringes with another person, even if the needle has been changed.
- If you are planning on getting pregnant, talk with your doctor. You may need to stop taking this drug at least 2 months before getting pregnant.
- If you have high blood sugar (diabetes), you must watch your blood sugar closely.

## STORAGE AND HANDLING OF WEGOVY<sup>TM</sup> (semaglutide)

- Store vials in a freezer. Thaw the frozen vial gently either by placing at room temperature for 20 to 30 minutes or held in the palm of the hand. Return the thawed vial to the freezer.
- Unopened containers stored in the refrigerator must be discarded after 3 days. Throw away any part not used after 28 days.
- Store in the original container to protect from light.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.