

Important Safety Information

What is the most important information I should know about Semaneo?

Semaneo may cause serious side effects, including:

Possible thyroid tumours, including cancer. Tell your healthcare 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, Semaneo and other medicines that work like Semaneo caused thyroid tumours, including thyroid cancer. It is not known if Semaneo will cause thyroid tumours or a type of thyroid cancer called medullary thyroid carcinoma (MTC) in people. Do not use Semaneo if you or any of your family have ever had a type of thyroid cancer called 'medullary thyroid carcinoma' (MTC) or if you have an endocrine system condition called 'Multiple Endocrine Neoplasia syndrome type 2' (MEN 2)

Do not use Semaneo if:

You or any of your family members have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC), or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)

You have had a serious allergic reaction to semaglutide or any of the ingredients in the Semaneo injection or Semaneo tablets. See symptoms of serious allergic reactions in "What are the possible side effects of Semaneo?"

Before using Semaneo, tell your healthcare provider if you have any other medical conditions, including if you:

- have or have had problems with your pancreas or kidneys
- have type 2 diabetes and a history of diabetic retinopathy
- are scheduled to have surgery or other procedures that use anaesthesia or deep sleepiness (deep sedation)
- are pregnant or plan to become pregnant. Semaneo may harm your unborn baby. You should stop using Semaneo 2 months before you plan to become pregnant
- are breastfeeding or plan to breastfeed. Breastfeeding is not recommended during treatment with Semaneo tablets. It is not known if Semaneo, when received through an injection, passes into your breast milk

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Semaneo may affect the way some medicines work, and some medicines may affect the way Semaneo works. Tell your healthcare provider if you are taking other medicines to treat diabetes, including sulfonylureas or insulin. Semaneo slows stomach emptying and can affect medicines that need to pass through the stomach quickly.

What are the possible side effects of Semaneo?

Semaneio may cause serious side effects, including:

inflammation of your pancreas (pancreatitis). Stop using Semaneio and call your healthcare provider right away if you have severe pain in your stomach area (abdomen) that will not go away, with or without nausea or vomiting. Sometimes you may feel the pain from your abdomen to your back

Gallbladder problems: Semaneio may cause gallbladder problems, including gallstones. Some gallstones may need surgery. Call your healthcare provider if you have symptoms, such as pain in your upper stomach (abdomen), fever, yellowing of the skin or eyes (jaundice), or clay-coloured stools.

Increased risk of low blood sugar (hypoglycaemia): Especially for those who also take medicines for diabetes, such as insulin or sulfonylureas. This can be a serious side effect. Talk to your healthcare provider about how to recognise and treat low blood sugar and check your blood sugar before you start and while you take Semaneio. Signs and symptoms of low blood sugar may include dizziness or light-headedness, blurred vision, anxiety, irritability or mood changes, sweating, slurred speech, hunger, confusion or drowsiness, shakiness, weakness, headache, fast heartbeat, or feeling jittery.

Dehydration leading to kidney problems: Diarrhoea, nausea, and vomiting may cause a loss of fluids (dehydration), which may cause kidney problems. It is important for you to drink fluids to help reduce your chance of dehydration. Tell your healthcare provider right away if you have nausea, vomiting, or diarrhoea that does not go away

Severe stomach problems: Stomach problems, sometimes severe, have been reported in people who use Semaneio. Tell your healthcare provider if you have stomach problems that are severe or will not go away

Serious allergic reactions: Stop using Semaneio 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

Change in vision in people with type 2 diabetes: Tell your healthcare provider if you have changes in vision during treatment with Semaneio

Increased heart rate: Semaneio can increase your heart rate while you are at rest. Tell your healthcare provider if you feel your heart racing or pounding in your chest, and it lasts for several minutes

Food or liquid gets into the lungs during surgery or other procedures that use anaesthesia, or deep sleepiness (deep sedation). Semaneio may increase the chance of food getting into your lungs during surgery or other procedures. Tell all your healthcare providers that you are taking Semaneio before you are scheduled to have surgery or other procedures

The most common side effects of Semaneo may include nausea, diarrhoea, vomiting, constipation, stomach (abdomen) pain, changes in skin sensations, headache, tiredness (fatigue), upset stomach, dizziness, feeling bloated, belching, low blood sugar in people with type 2 diabetes, gas, stomach flu, heartburn, and hair loss.