

RYBELSUS Information

Official communication about medicines containing semaglutide from Novo Nordisk

<https://www.novomedlink.com/semaglutide/updates.html>

What is RYBELSUS®?

RYBELSUS® (semaglutide) tablets 7 mg or 14 mg is a prescription medicine used along with diet and exercise to improve blood sugar (glucose) in adults with type 2 diabetes.

- It is not known if RYBELSUS® can be used in people who have had pancreatitis
- RYBELSUS® is not for use in people with type 1 diabetes
- It is not known if RYBELSUS® is safe and effective for use in children under 18 years of age

Important Safety Information

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

RYBELSUS® may cause serious side effects, including:

- **Possible thyroid tumors, 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, RYBELSUS® and medicines that work like RYBELSUS® caused thyroid tumors, including thyroid cancer. It is not known if RYBELSUS® will cause thyroid tumors or a type of thyroid cancer called medullary thyroid carcinoma (MTC) in people

Do not use RYBELSUS® 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)
- you have had a serious allergic reaction to semaglutide or any of the ingredients in RYBELSUS®. See symptoms of serious allergic reaction in **“What are the possible side effects of RYBELSUS®?”**

Before using RYBELSUS®, 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 a history of vision problems related to your diabetes
- are pregnant or plan to become pregnant. It is not known if RYBELSUS® will harm your unborn baby. You should stop using RYBELSUS® 2 months before you plan to become pregnant. Talk to your healthcare provider about the best way to control your blood sugar if you plan to become pregnant or while you are pregnant
- are breastfeeding or plan to breastfeed. Breastfeeding is not recommended during treatment with RYBELSUS®

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. RYBELSUS® may affect the way some medicines work and some medicines may affect the way RYBELSUS® works.

How should I take RYBELSUS®?

- Take RYBELSUS® exactly as your healthcare provider tells you to
- Take RYBELSUS® by mouth on an empty stomach when you first wake up with a sip of plain water (no more than 4 ounces)
- Do not split, crush, or chew. Swallow RYBELSUS® whole
- After 30 minutes, you can eat, drink, or take other oral medicines
- If you miss a dose of RYBELSUS®, skip the missed dose and go back to your regular schedule

What are the possible side effects of RYBELSUS®?

RYBELSUS® may cause serious side effects, including:

- **inflammation of your pancreas (pancreatitis).** Stop using RYBELSUS® 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 vomiting. You may feel the pain from your abdomen to your back
- **changes in vision.** Tell your healthcare provider if you have changes in vision during treatment with RYBELSUS®
- **low blood sugar (hypoglycemia).** Your risk for getting low blood sugar may be higher if you use RYBELSUS® 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 RYBELSUS® 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 RYBELSUS®. Tell your healthcare provider right away if you get symptoms of gallbladder problems, which may include: pain in your upper stomach (abdomen), yellowing of skin or eyes (jaundice), fever, and clay-colored stools

The most common side effects of RYBELSUS® may include nausea, stomach (abdominal) pain, diarrhea, decreased appetite, vomiting, and constipation. Nausea, vomiting, and diarrhea are most common when you first start RYBELSUS®.

Please see [Prescribing Information](#) and [Medication Guide](#) for RYBELSUS®.

RYBELSUS® is a prescription medication.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.