

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

**Rybelsus 3 mg
Rybelsus 7 mg
Rybelsus 14 mg
Tablets**

Active ingredient:

Rybelsus 3 mg: each tablet contains semaglutide 3 mg

Rybelsus 7 mg: each tablet contains semaglutide 7 mg

Rybelsus 14 mg: each tablet contains semaglutide 14 mg

Inactive ingredients and allergens in this medicine: see section 2 "Important information about some of this medicine's ingredients", and section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Rybelsus is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise:

- as monotherapy – when metformin is considered inappropriate due to intolerance or contraindications.
- in combination with other medicinal products for the treatment of diabetes.

It is important that you continue with your diet and exercise plan as agreed with your doctor, pharmacist or nurse.

Therapeutic group: Medicines for diabetes. GLP-1 (Glucagon-like peptide-1) analog.

What is type 2 diabetes?

Type 2 diabetes is a condition in which your body does not make enough insulin, and the insulin that your body makes does not lower your blood sugar the way it should. In some cases, your body can produce too much blood sugar. If your blood sugar increases and remains high over a long period of time, this may lead to harmful effects such as heart problems, kidney disease, eye disorders and poor circulation in your limbs. That is why it is important to keep your blood sugar levels within a normal range.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to semaglutide or to any of the other ingredients in this medicine (see section 6 "Additional information").

Special warnings about using this medicine

Before treatment with Rybelsus, talk to your doctor.

General warnings:

This medicine is not the same as insulin and you should not use it if:

- you have type 1 diabetes (your body does not produce any insulin)

- you develop diabetic ketoacidosis. This is a complication of diabetes associated with high blood sugar, breathing difficulty, confusion, excessive thirst, a sweet smell of the breath or a sweet or metallic taste in the mouth.

Stomach and gut problems and dehydration

During treatment with this medicine, you may feel sick (nausea) or be sick (vomiting), or have diarrhoea. These side effects can cause dehydration (loss of fluids). It is important that you drink enough fluids to prevent dehydration. This is especially important if you have kidney problems. Talk to your doctor if you have any questions or concerns.

Severe and on-going stomach pain which could be due to an inflamed pancreas

If you have severe and on-going pain in the stomach area – see a doctor straight away as this could be a sign of inflamed pancreas (acute pancreatitis).

Low blood sugar (hypoglycaemia)

Taking a sulfonylurea medicine or insulin with Rybelsus might increase the risk of getting low blood sugar (hypoglycaemia). See section 4 for the warning signs of low blood sugar levels.

Your doctor may ask you to test your blood sugar levels. This will help to decide if the dose of the sulfonylurea or insulin needs to be changed to reduce the risk of low blood sugar.

Diabetic eye disease (retinopathy)

Fast improvements in blood sugar control may lead to a temporary worsening of diabetic eye disease. If you have diabetic eye disease and get eye problems while taking this medicine, talk to your doctor.

Treatment response

If the treatment response with semaglutide is lower than expected, this may be due to low absorption caused by variability in absorption and low absolute bioavailability. You should follow the instructions given in section 3 for optimal effect of semaglutide.

Children and adolescents

This medicine is not intended for children and adolescents aged under 18 years as the safety and efficacy in this age group have not been established.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- levothyroxine which is used for thyroid disease. This is because your doctor may need to check your thyroid levels if you are taking Rybelsus together with levothyroxine.
- warfarin or similar medicines taken by mouth to reduce blood clotting (oral anti-coagulants). You may need frequent blood tests to check how quickly your blood clots.
- If you are using insulin, your doctor will tell you how to reduce the dose of insulin and will recommend you to monitor your blood sugar more frequently, in order to avoid hyperglycaemia (high blood sugar) and diabetic ketoacidosis (a complication of diabetes that occurs when the body is unable to breakdown glucose because there is not enough insulin).

Using this medicine and food

Take the medicine on an empty stomach with a small quantity of water (up to 120 ml). Wait at least 30 minutes before eating or drinking after taking the medicine. Waiting less than 30 minutes lowers the absorption of semaglutide.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, ask your doctor for advice before taking this medicine.

This medicine should not be used during pregnancy, as it is not known if it affects your unborn baby. Therefore, use of contraception is recommended during treatment with this medicine. If you wish to become pregnant, discuss how to change your treatment with your doctor as you should stop taking this medicine at least 2 months in advance. If you become pregnant while using this medicine, talk to your doctor straight away, as your treatment will need to be changed.

Do not use this medicine if you are breast-feeding, as it is unknown if it passes into breast milk.

Driving and using machines

Rybelsus is unlikely to affect your ability to drive and use machines.

Some patients may feel dizzy when taking Rybelsus. If you feel dizzy, be extra careful while driving or using machines. Talk to your doctor for further information.

If you use this medicine in combination with a sulfonylurea medicine or insulin, low blood sugar (hypoglycaemia) may occur which may reduce your ability to concentrate. Do not drive or use machines if you get any signs of low blood sugar. See section 2, sub-section "Special warnings about using this medicine" for information on increased risk of low blood sugar and section 4 for the warning signs of low blood sugar. Talk to your doctor for further information.

Important information about some of this medicine's ingredients

This medicine contains 23 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 1% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine. The recommended dosage is usually:

- The starting dose is one 3 mg tablet once a day for one month.
- After one month, your doctor will increase your dose to 7 mg once a day.
- Your doctor may increase your dose to 14 mg once a day if your blood sugar is not controlled well enough with a dose of 7 mg once a day.

Your doctor will prescribe the strength that is right for you. Do not change your dose unless your doctor has told you so. It is not recommended to take two 7 mg tablets to get the effect of one 14 mg tablet, as this has not been studied.

Do not exceed the recommended dose.

Manner of taking the medicine

- Take the Rybelsus tablet on an empty stomach at any time of the day.
- Swallow the Rybelsus tablet whole with a sip of water (up to 120 ml).
- After taking the Rybelsus tablet, wait at least 30 minutes before having a meal or drink or taking other oral medicines.

Crushing/splitting/chewing

It is not recommended to split, crush or chew the tablet, as it is not known if it affects the absorption of semaglutide.

If you have accidentally taken a higher dose

If you have taken an overdose, or if a child has accidentally taken some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. You may get side effects such as feeling sick (nausea).

If you forget to take the medicine

If you forget to take a dose, skip the missed dose and just take your normal dose the next day.

Adhere to the treatment as recommended by your doctor.

If you stop taking this medicine

Even if your health improves, do not stop taking this medicine without consulting your doctor. If you stop using the medicine, your blood sugar level may increase.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicines, using Rybelsus may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Serious side effects

Refer immediately to the doctor if any of the serious side effects listed below appears.

Common side effects (may affect up to 1 in 10 users)

- complications of diabetic eye disease (retinopathy). **You should tell your doctor** if you get eye problems, such as changes in vision, during treatment with this medicine.

Rare side effects (may affect up to 1 in 1,000 users):

- serious allergic reactions (anaphylactic reactions). You must get immediate medical help and inform your doctor straight away if you get symptoms such as breathing problems, swelling of face and throat, wheezing, fast heartbeat, pale and cold skin, feeling dizzy or weak.
- inflamed pancreas (acute pancreatitis) which could cause severe pain in the stomach and back which does not go away. You should see a doctor immediately if you experience such symptoms.

Side effects of unknown frequency (frequency cannot be estimated from the available data)

- Bowel obstruction. A severe form of constipation with additional symptoms such as stomach ache, bloating, vomiting etc.

Other side effects

Very common side effects (may affect more than 1 in 10 users)

- feeling sick (nausea) – this usually goes away over time
- diarrhoea – this usually goes away over time
- low blood sugar (hypoglycaemia) - when this medicine is used with medicines that contain a sulfonylurea or insulin. Your doctor may reduce your dose of these medicines before you start using this medicine.

The warning signs of low blood sugar may come on suddenly. They can include cold sweat, cool pale skin, headache, fast heartbeat, feeling sick (nausea) or very hungry, changes in vision, feeling sleepy or weak, feeling nervous, anxious or confused, difficulty concentrating or shaking.

Your doctor will tell you how to treat low blood sugar and what to do if you notice these warning signs.

Common side effects (may affect up to 1 in 10 users)

- low blood sugar (hypoglycaemia) when this medicine is used with oral diabetes medicine other than sulfonylurea or insulin
- being sick (vomiting)
- upset stomach or indigestion
- inflamed stomach ('gastritis') – the signs include stomach ache, feeling sick (nausea) or being sick (vomiting)
- reflux or heartburn – also called 'gastro-esophageal reflux disease'
- stomach pain
- bloating of the stomach
- constipation
- tiredness
- less appetite
- gas (flatulence)
- increase of pancreatic enzymes (such as lipase and amylase) shown in blood tests
- feeling dizzy.

Uncommon side effects (may affect up to 1 in 100 users)

- weight loss
- gallstones
- burping
- fast pulse
- allergic reactions like rash, itching or hives
- a delay in the emptying of the stomach
- change in the way food or drink tastes.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the blister and outer package. The expiry date refers to the last day of that month.

Storage conditions

Store in the original package in order to protect from light and moisture. Store up to 30°C. Do not throw away the medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:

salcaprozate sodium, cellulose microcrystalline, magnesium stearate, povidone K90

What the medicine looks like and contents of the pack:

Rybelsus 3 mg: white to light yellow and oval shaped (7.5 mm x 13.5 mm) tablets. They have '3' on one side and 'novo' on the other side.

Rybelsus 7 mg: white to light yellow and oval shaped (7.5 mm x 13.5 mm) tablets. They have '7' on one side and 'novo' on the other side.

Rybelsus 14 mg: white to light yellow and oval shaped (7.5 mm x 13.5 mm) tablets. They have '14' on one side and 'novo' on the other side.

The tablets are available in aluminum blisters.

Rybelsus 3 mg tablets are available in pack of 30 tablets.

Rybelsus 7 mg and 14 mg tablets are available in packs of 30 and 90 tablets.

Not all pack sizes may be marketed.

Registration holder's name and address:

Novo Nordisk Ltd.,
1 Atir Yeda St.,
Kfar Saba 4464301

Manufacturer's name and address:

Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, Denmark.

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Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Rybelsus 3 mg: 166-72-36539

Rybelsus 7 mg: 166-73-36540

Rybelsus 14 mg: 166-74-36541

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