

RYBELSUS® TABLET

Semaglutide (3 mg, 7 mg, 14 mg)

What is in this leaflet

1. What Rybelsus® is used for
2. How Rybelsus® works
3. Before you use Rybelsus®
4. How to use Rybelsus®
5. While you are using it
6. Side effects
7. Storage and disposal of Rybelsus®
8. Product description
9. Manufacturer
10. Product Registration Holder
11. Date of revision

1. What Rybelsus® is used for

Rybelsus® is used to treat adults (aged 18 years and older) with type 2 diabetes when diet and exercise is not enough:

- ▶ on its own – when you cannot use metformin (another diabetes medicine) or
- ▶ with other medicines for diabetes – when the other medicines are not enough to control your blood sugar levels. These may be medicines you take by mouth or inject such as insulin.

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

2. How Rybelsus® works

Rybelsus® contains the active substance semaglutide. It is a medicine that is used to lower blood sugar levels.

3. Before you use Rybelsus®

- When you must not use it

Do not take Rybelsus®

- ▶ If you are allergic to semaglutide or any of the other ingredients of this medicine (listed in section 8. Product Description').

- Before you start to use it

Talk to your doctor, pharmacist or nurse before using Rybelsus®.

Warnings and precautions

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 with high blood sugar, breathing difficulty, confusion, excessive thirst, a sweet smell to the breath or a sweet or metallic taste in the mouth.

If you know that you are due to have surgery where you will be under anaesthesia (sleeping), please tell your doctor that you are taking Rybelsus®.

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 acute pancreatitis

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). 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 recommended in children and adolescents aged under 18 years as the safety and efficacy in this age group have not been established.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor, pharmacist or nurse if you are using medicines containing any of the following:

- ▶ 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).

Sodium content

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.

4. How to use Rybelsus®

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- How much to use

- ▶ 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.

- When to use it

- ▶ Take your Rybelsus® tablet on an empty stomach at any time of the day.
- ▶ Swallow your Rybelsus® tablet whole with a sip of water (up to 120 ml). Do not split, crush or chew the tablet, as it is not known if it affects absorption of semaglutide.
- ▶ After taking your Rybelsus® tablet wait at least 30 minutes before having your first meal or drink of the day or taking other oral medicines. Waiting less than 30 minutes lowers the absorption of semaglutide.

- How long to use it

Do not stop using this medicine without talking to your doctor. If you stop using it, your blood sugar levels may increase.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

- If you forget to use it

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

- If you use too much (overdose)

If you take more Rybelsus® than you should, talk to your doctor straight away. You may get side effects such as feeling sick (nausea).

5. While you are using it

- Things you must do

Always use this medicine exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

- Things you must not do

Do not stop using this medicine without talking to your doctor.

- Things to be careful of

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, 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 while taking this medicine. If you wish to become pregnant, discuss how to change your treatment with your doctor as you should stop using 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. The medicine passes into breast milk, and it is not known how it affects your baby.

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 the further information.

If you use this medicine in combination with a sulfonylurea 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 3, 'Warning and precautions' for information on increased risk of low blood sugar and section 6 for the warning signs of low blood sugar. Talk to your doctor for further information.

6. Side effects

Like all medicines, Rybelsus® can cause side effects, although not everybody gets them.

Serious side effects

Common (may affect up to 1 in 10 people)

- ▶ 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 (may affect up to 1 in 1,000 people)

- ▶ 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.

Not known (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 (may affect more than 1 in 10 people)

- ▶ 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 (may affect up to 1 in 10 people)

- ▶ 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 (may affect up to 1 in 100 people)

- ▶ 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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

7. Storage and disposal of Rybelsus®

- Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and carton after 'Expiry'. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light and moisture. Store below 30°C.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

8. Product description

- What it looks like

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

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

Rybelsus® 14 mg tablets are white to

light yellow and oval shaped (7.5 mm x 13.5 mm). They have '14' on one side and 'novo' on the other side.

The 3 mg, 7 mg and 14 mg tablets are available in alu/alu blister cards in pack sizes of 30, 60 and 90 tablets.

Not all pack sizes may be marketed in your country.

- Ingredients

- Active ingredient

Semaglutide.

Each tablet contains 3, 7 or 14 mg semaglutide.

- Inactive ingredients

Salcaproate sodium, povidone K90, cellulose microcrystalline, magnesium stearate.

- MAL number

3mg: MAL22056044AZ

7mg: MAL22056045AZ

14mg: MAL22056046AZ

9. Manufacturer

Manufactured by

Novo Nordisk A/S
Novo Nordisk Park
DK-2760 Måløv
Denmark

Released by

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

10. Product Registration Holder

Novo Nordisk Pharma (Malaysia) Sdn. Bhd.
Menara 1 Sentrum, Level 16
No. 201 Jalan Tun Sambanthan 50470
Kuala Lumpur
Malaysia

11. Date of revision

24 April 2025

Serial number

NPRA(R3/01)18122024/0337