Applicant	Novo Nordisk (Pty) Ltd	**Dosage form and strength**	Tablet; 3 mg Semaglutide Tablet; 7 mg Semaglutide Tablet ; 14 mg Semaglutide
Product name	Rybelsus 3 mg Rybelsus 7 mg Rybelsus 14 mg	**Application number**	560337 560338 560339
Date of approval	03 September 2024	**Module 1**	1.3.2.1 PIL (approved)

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

RYBELSUS 3 mg tablets

Semaglutide 3 mg

RYBELSUS 7 mg tablets

Semaglutide 7 mg

RYBELSUS 14 mg tablets

Semaglutide 14 mg

Read all of this leaflet carefully before you start taking RYBELSUS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- RYBELSUS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What RYBELSUS is and what it is used for

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

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 taken by mouth or given by injection such as insulin.

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

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 can 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. What you need to know before you take RYBELSUS

Do not take RYBELSUS:

- if you are hypersensitive (allergic) to semaglutide or any of the other ingredients of this RYBELSUS (listed in section 6).

Warnings and precautions

Talk to your doctor or healthcare provider before taking RYBELSUS

Take special care with RYBELSUS:

This medicine is not an insulin and should not be used if:

- you have type 1 diabetes – the type of diabetes where your body does not produce any insulin
- you develop diabetic ketoacidosis – 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.

Stomach and gut problems

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 them 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 experience 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 under 18 years as the safety and efficacy in this age group have not been established.

Other medicines and RYBELSUS

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional 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).

RYBELSUS with food, drink and alcohol

See section 3.

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 may affect your unborn child. Therefore, it is recommended to use contraception while using 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 two months in advance. If you become pregnant when 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

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 2, ‘Warning and precautions’ 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.

RYBELSUS contains sodium

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 take RYBELSUS

Do not share medicines prescribed for you with any other person.

Always take RYBELSUS exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is...

How much to take

- 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.

Taking this medicine

- Take your RYBELSUS tablet on an empty stomach.
- 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.

If you take more RYBELSUS than you should

If you take more RYBELSUS than you should, talk to your doctor straight away. You may get side effects such as feeling sick (nausea).
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take RYBELSUS

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

If you stop taking RYBELSUS

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.

4. Possible side effects

RYBELSUS can have side effects.
Not all side effects reported for RYBELSUS are included in this leaflet.
Should your general health worsen or if you experience any untoward effects while taking RYBELSUS, please consult your health care provider for advice.

Serious side effects
If any of the following happens, stop taking RYBELSUS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing; low blood pressure

(paleness and coldness of skin, rapid heartbeat), feeling dizzy, sweating;

- rash, hives or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to RYBELSUS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain,
- angina,
- changes in the way your heart beats, for example, if you notice it beating faster,
- difficulty breathing,
- signs of recurrent infections such as fever or sore throat,
- less urine than is normal for you,
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems

These are all serious side effects. You may need urgent medical attention.

Very frequent side effects:

- 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.

Frequent side effects:

- 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.
- 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, reflux or heartburn – also called ‘gastro-oesophageal 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 tests.

Less frequent side effects:

- serious allergic reactions (anaphylactic reactions). You should seek 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.
- weight loss
- gallstones
- burping
- fast pulse.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of RYBELSUS.

5. How to store RYBELSUS

Store all medicines out of reach of children.

Store at or below 30 °C

Do not refrigerate

Do not use RYBELSUS after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

Do not use this medicine if you notice that the package is damaged or shows signs of being open.

Keep the container in the outer carton until required for use.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage system (e.g. toilets).

6. Contents of the pack and other information

What RYBELSUS contains

- The active substance is semaglutide. Each tablet contains 3, 7 or 14 mg semaglutide

The other ingredients are:

- The other ingredients are salcaprozate sodium, povidone, microcrystalline cellulose, magnesium stearate

What RYBELSUS looks like and contents of the pack

- RYBELSUS 3 mg tablets are white to light yellow and oval shaped. They have '3' on one side and 'novo' on the other side. The blister foil is bright green in colour.
- RYBELSUS 7 mg tablets are white to light yellow and oval shaped. They have '7' on one side and 'novo' on the other side. The blister foil is bright red in colour.
- RYBELSUS 14 mg tablets are white to light yellow and oval shaped. They have '14' on one side and 'novo' on the other side. The blister foil is bright blue in colour.
- The tablets are available in alu/alu blister cards in pack sizes of 30, 60 and 90 tablets.
- Not all pack sizes may be marketed

Holder of Certificate of Registration

Novo Nordisk (Pty) Ltd

150 Rivonia Road

10 Marion Street Office Park

Building C1

Sandton, Johannesburg

2196

This leaflet was last revised in

Date of registration: 3 September 2024

Applicant	Novo Nordisk (Pty) Ltd	**Dosage form and strength**	Tablet; 3 mg Semaglutide Tablet; 7 mg Semaglutide Tablet ; 14 mg Semaglutide
Product name	Rybelsus 3 mg Rybelsus 7 mg Rybelsus 14 mg	**Application number**	560337 560338 560339
Date of approval	03 September 2024	**Module 1**	1.3.2.1 PIL (approved)

Application number

Rybelsus 3 mg: 56/21.13/0337

Rybelsus 7 mg: 56/21.13/0338

Rybelsus 14 mg: 56/21.13/0339