

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PRRYBELSUS**[®] semaglutide tablets**

Read this carefully before you start taking Rybelsus[®] and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Rybelsus[®].

What is Rybelsus[®] used for?

Rybelsus[®] contains the active substance semaglutide. It is used to lower blood sugar (glucose) in adults with type 2 diabetes.

- Rybelsus[®] is used on its own if your blood sugar level is not properly controlled by diet and exercise alone and you cannot use metformin.
- Rybelsus[®] is used in combination with one or more other medicines for diabetes when they are not enough to control your blood sugar levels.

How does Rybelsus[®] work?

Rybelsus[®] belongs to a class of medicines called GLP-1 receptor agonists (glucagon-like peptide-1 receptor agonists). Rybelsus[®] helps your body make more insulin when your blood sugar is high.

What are the ingredients in Rybelsus[®]?

Medicinal ingredients: semaglutide

Non-medicinal ingredients: magnesium stearate, microcrystalline cellulose, povidone K 90, salcaprozate sodium (SNAC)

Rybelsus[®] comes in the following dosage forms:

3 mg tablets are white to light yellow, oval shaped debossed with “3” on one side and “novo” on the other side. The tablets are supplied in green coloured cartons and blister packaging.

7 mg tablets are white to light yellow, oval shaped debossed with “7” on one side and “novo” on the other side. The tablets are supplied in red coloured cartons and blister packaging.

14 mg tablets are white to light yellow, oval shaped debossed with “14” on one side and “novo” on the other side. The tablets are supplied in blue coloured cartons and blister packaging.

Do not use Rybelsus[®] if:

- you are allergic to semaglutide or any of the other ingredients in this medication;
- you or a member of your family has ever had medullary thyroid cancer (MTC);
- you have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2);
- you are pregnant or breastfeeding.

To help avoid side effects and ensure proper use, talk to your healthcare professional

before you take Rybelsus®. Talk about any health conditions or problems you may have, including if you:

- or a member of your family has or has had medullary thyroid carcinoma (MTC), or if you have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2);
- have type 1 diabetes – a condition where your body does not produce any insulin;
- you develop diabetic ketoacidosis (increased ketones in the blood or urine);
- have ever had an allergic reaction to Rybelsus®;
- have a high heart rate (fast pulse);
- have ever had pancreatitis;
- are breastfeeding or plan to breastfeed;
- are pregnant or plan to become pregnant;
- have end stage renal disease;
- have gastrointestinal (digestive) problems, including severe vomiting, diarrhea and/or dehydration;
- have liver or gall bladder problems;
- have diabetic retinopathy.

Other warnings you should know about:

Children and adolescents

Rybelsus® is not recommended in children and adolescents under 18 years as the safety and efficacy in this age group have not yet been studied.

Pregnancy and Breastfeeding

Tell your doctor if you are pregnant, think you might be pregnant, or are planning to become pregnant. Rybelsus® should not be used during pregnancy and for at least two months before a planned pregnancy because it is not known if it may affect your unborn child.

If you could become pregnant while using Rybelsus®, it is recommended to use contraception.

Do not use this medicine if you are breastfeeding. This is because it is not known if Rybelsus® passes into breastmilk.

Driving and Using Machines

If you use this medicine in combination with a sulfonylurea or insulin, low blood sugar (hypoglycemia) may occur which may reduce your ability to concentrate. Avoid driving or using machines if you get any signs of low blood sugar. Talk to your doctor for further information.

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 acute pancreatitis (inflamed pancreas).

Effects on the digestive system, including dehydration

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

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 medication, talk to your doctor.

Low blood sugar (hypoglycemia)

Taking a sulfonylurea medicine or insulin with Rybelsus[®] might increase the risk of getting low blood sugar levels (hypoglycemia). Your doctor may ask you to test your blood sugar levels. This will help your doctor decide if the dose of the sulfonylurea or insulin needs to be changed to reduce the risk of low blood sugar.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

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

- sulfonylurea;
- insulin;
- levothyroxine – this is because your doctor may need to check your thyroid levels if you are taking Rybelsus[®] together with levothyroxine.

The following may interact with Rybelsus[®]:

The following list includes some, but not all, of the drugs that may increase your heart rate. You should check with your doctor or pharmacist before taking any other medication with Rybelsus[®]:

- drugs to treat hypertension;
- drugs to treat heart failure;
- drugs to treat HIV infection;
- drugs to treat attention deficit-hyperactivity disorder;
- drugs to suppress appetite/cause weight loss;
- decongestants;
- drugs to treat asthma.

How to take Rybelsus[®]:

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

Follow these instructions carefully:

- 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.
- After taking your Rybelsus[®] tablet wait at least 30 minutes before you have your first meal or drink of the day or taking other oral medicines.

Usual dose:

- The starting dose is one 3 mg tablet once a day for 30 days.
- After 30 days of 3 mg once a day, 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. Do not take more than one tablet of Rybelsus® daily. Do not take two tablets of Rybelsus® to obtain a higher dose.

Do not stop this medicine without talking to your doctor. If you stop taking 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.

Overdose:

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

If you think you have taken too much Rybelsus®, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed dose:

If you forget to take a dose, just take one tablet on the morning after.

What are possible side effects from using Rybelsus®?

These are not all the possible side effects you may feel when taking Rybelsus®. If you experience any side effects not listed here, contact your healthcare professional.

Very common: may affect more than 1 in 10 people

- feeling sick (nausea) – this usually goes away over time;
- diarrhea – this usually goes away over time;
- low blood sugar (hypoglycemia) when this medicine is used with insulin or sulfonylureas.

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.

Low blood sugar is more likely to happen if you also take a sulfonylurea or insulin. Your doctor may reduce your dose of these medicines before you start using this medicine.

Common: may affect up to 1 in 10 people

- 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' (GERD);

- stomach pain;
- bloating of the stomach;
- constipation;
- change in the way food or drink tastes;
- tiredness;
- less appetite;
- gas (flatulence);
- increase of pancreatic enzymes (such as lipase and amylase).

Uncommon: may affect up to 1 in 100 people

- weight loss;
- gallstones;
- burping;
- fast pulse;
- allergic reactions like rash, itching or hives

Rare: may affect up to 1 in 1,000 people

- 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.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Diabetic retinopathy complications – complications of diabetic eye disease/diabetic eye problems		√	
UNCOMMON			
Pancreatitis (severe and ongoing pain in the stomach area which could be a sign of inflamed pancreas)		√	√
Severe hypoglycemia* (low blood sugar) symptoms: feeling confused, fits and passing out.		√	
RARE			

Severe allergic reaction (anaphylactic reaction) symptoms: breathing problems, swelling of face and throat and a fast heartbeat.		√	√
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**The risk of severe hypoglycemia is higher depending on the other diabetes medications.*

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

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

Store Rybelsus[®] at room temperature (15 °C to 30 °C). Rybelsus[®] must be stored in the original blister package to protect from moisture and light. Keep the tablet in the blister until you are ready to take it. Removing it too soon can prevent it from working as planned.

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

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

If you want more information about Rybelsus[®]:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.novonordisk.ca, or by calling 1-800-465-4334.

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