

# **RYBELSUS®**

semaglutide tablets

## Supporting you with your RYBELSUS® treatment

**This booklet is for UK-based adults living with type 2 diabetes who have been prescribed RYBELSUS®**

Information on warnings and precautions for RYBELSUS® can be found on pages 6–10 of this booklet.

Information on possible side effects for RYBELSUS® can be found on pages 14–18 of this booklet.

This material is designed to be viewed digitally.

It contains hyperlinks which are viewable online only.



This is not a real patient and is for illustrative purposes only.

Please refer to the Package Leaflet: Information for the patient found in the product carton for:

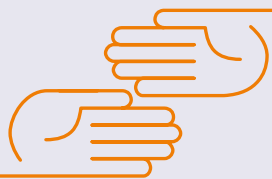
- Further information on RYBELSUS®
- Further information on how to use RYBELSUS®
- A full list of side effects, warnings and precautions



### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store. Side effects should also be reported to Novo Nordisk Limited (Telephone Novo Nordisk Customer Care Centre 0800 023 2573). Calls may be monitored for training purposes. By reporting side effects you can help provide more information on the safety of this medicine.

This material has been produced and funded by Novo Nordisk for UK-based adult patients who have already been prescribed RYBELSUS®. This information does not replace the Package Leaflet: Information for the patient, which you are advised to read in full. It is not intended as a substitute for clinical advice provided by your healthcare professional. Please contact your healthcare professional if you have any questions about your treatment and for clinical advice.



This booklet has been made with you in mind, to help support you throughout your treatment.

It will give you:

- Information about RYBELSUS®
- An explanation of how RYBELSUS® works
- Some things to remember when using RYBELSUS®

If there are any words in this booklet that are new or difficult to understand, please look at the section at the back called '**Useful words to know**'.



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# Contents

1. Why have you been prescribed RYBELSUS®?	4
2. How RYBELSUS® works	5
3. What you need to know before you take RYBELSUS®	6
4. How to take RYBELSUS®	10
5. Things to remember when taking RYBELSUS®	12
6. What to do if you miss your dose	13
7. Possible side effects	14
8. Storage	19
9. Staying active is a key part of managing diabetes	20
10. Healthy eating habits	21
11. Useful words to know	22



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## Why have you been prescribed RYBELSUS®?

Having type 2 diabetes means that managing your blood sugar levels is very important.

You and your healthcare professional have decided that RYBELSUS® is the appropriate kind of medication to help you do this.

More information on what is covered in the rest of this booklet can be found in the **Package Leaflet: Information for the patient** enclosed with your medication. Please take the time to read through this in full. If you still have any questions or queries, please speak with your healthcare professional.



# How RYBELSUS® works

RYBELSUS® contains the active substance semaglutide. It is a medicine that is used to lower blood sugar levels. It is a GLP-1 RA (glucagon-like peptide-1 receptor agonist) that is:

- A medication for adults with type 2 diabetes
- Not an insulin

RYBELSUS® is similar to a natural hormone called GLP-1, released into the blood after eating. Using RYBELSUS® alongside the diet and exercise plan given to you by your doctor, pharmacist or nurse can help lower your 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 you take by mouth or inject such as insulin



# What you need to know before you take RYBELSUS®

Please refer to the Package Leaflet: Information for the patient found in the product carton for a full list of warnings and precautions.

## Do not take RYBELSUS®

- If you are allergic to semaglutide or any of the other ingredients of this medicine

## Warnings and precautions

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

## Traceability

In order to improve the traceability of biological medicinal products, record the name and the lot number (included on the outer cartons and blister pack) of the medicine you are taking and provide this information when reporting any side effects.

## General

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 general 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 ongoing stomach pain which could be due to an inflamed pancreas**

If you have ever had pancreatitis (inflammation of the pancreas) which may cause severe pain in the stomach and back which does not go away. This is a serious, potentially life-threatening condition. You should see a doctor immediately if you experience such symptoms. Stop using this medicine and seek urgent medical help if you experience: Severe, persistent pain in the stomach area (abdomen), with or without nausea and vomiting. This could be a sign of acute pancreatitis, which is serious and potentially life-threatening.

## **Low blood sugar (hypoglycaemia)**

Taking a sulfonylurea medicine or insulin with RYBELSUS® might increase the risk of getting low blood sugar (hypoglycaemia). See page 15 of this booklet, or the Package Leaflet: Information for the patient for symptoms of low blood sugar.

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. See pages 10 to 12 of this booklet for optimal effect of semaglutide.

## Sudden changes to your eyesight

If you notice a sudden loss of vision or rapidly worsening eyesight during treatment with RYBELSUS®, urgently contact your doctor. This may be caused by a very rare side effect called non-arteritic anterior ischaemic optic neuropathy (NAION). Your doctor will refer you for an eye examination by an ophthalmologist and you may have to stop treatment with RYBELSUS®.

## 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.

## Other medicines and RYBELSUS®

**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 break down glucose because there is not enough insulin)



## **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 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 page 7 of this booklet for information on increased risk of low blood sugar when taking a sulfonylurea medicine or insulin with RYBELSUS®. See page 15 of this booklet or the Package Leaflet: Information for the patient for 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.

Always use RYBELSUS® as your doctor, pharmacist or nurse has told you to. If you are unsure or have any questions, please check with them.

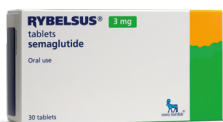


## How to take RYBELSUS®

RYBELSUS® is currently undergoing a transition to a new formulation. Currently, both the previous formulation and new formulation are available. The previous formulation will be discontinued eventually. Please find guidance on dose escalation and how to take your RYBELSUS® tablets on the next page.

### Previous RYBELSUS® tablets

### New RYBELSUS® tablets



**3 mg**

=



**1.5 mg**



**7 mg**

=



**4 mg**



**14 mg**

=



**9 mg**

The pack shots and tablet images are for illustrative purposes only and do not reflect the actual size of the pack or tablet.

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on RYBELSUS®.

The starting dose is **one 3 mg tablet or 1.5 mg tablet once a day** for **1 month**.

After **1 month**, your doctor will increase your dose to **one 7 mg tablet or 4 mg tablet once a day**, depending on which formulation you started on.

Your doctor may increase your dose to **one 14 mg tablet or 9 mg tablet once a day** if your blood sugar is not controlled well enough with a dose of **7 mg or 4 mg once a day**, depending on which formulation you are on.

RYBELSUS® should always be taken as one tablet per day. You should not take two tablets to get the effect of a higher dose.

**Please refer to the Package Leaflet: Information for the patient enclosed with your medication for details on how to take RYBELSUS®.**

Do not change your RYBELSUS® dose unless your healthcare professional has told you to. Do not stop using insulin without talking to your doctor.

**1. Take on an empty stomach**, after a recommended fasting period of at least 8 hours



**2. Take your tablet whole with a sip of water (up to 120 ml)**



**3. Wait at least 30 minutes\*** before eating, drinking, or taking any other oral medication



\*Waiting less than 30 minutes decreases the absorption of RYBELSUS®.



## Things to remember when taking RYBELSUS®

### Important dosing instructions

- Do not split, crush, or chew the tablet when taking it, as RYBELSUS® should be swallowed whole
- RYBELSUS® should always be taken as one tablet per day. You should not take two tablets to get the effect of a higher dose
- Keep the tablets in their packaging until you are ready to take one, in order to protect them from moisture and light

- RYBELSUS® is currently undergoing a transition to a new formulation. Currently, both the previous formulation and new formulation are available, meaning that RYBELSUS® is available in six doses, in three different coloured blister packs. The previous formulation will be discontinued eventually. Your healthcare professional will decide which ones you will be prescribed
- All doses are available in pack sizes of 30 tablets



## What to do if you miss your dose

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

**Never** take a double dose to make up for a forgotten dose.

## If you take more RYBELSUS® than you should

Talk to your doctor straight away. You may get side effects such as feeling sick (nausea).

## 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.



# Possible side effects

**Please refer to the Package Leaflet: Information for the patient found in the product carton for a full list of possible side effects.**

Like all medicines, this medicine 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. This is a serious, potentially life-threatening condition. You should see a doctor immediately if you experience such symptoms. Stop using this medicine and seek urgent medical help if you experience: Severe, persistent pain in the stomach area (abdomen), with or without nausea and vomiting. This could be a sign of acute pancreatitis, which is serious and potentially life-threatening

**Very rare** (may affect up to 1 in 10,000 people)



A medical condition of the eye called non-arteritic anterior ischaemic optic neuropathy (NAION), which may cause loss of vision without any pain. You should urgently contact your doctor if you notice sudden or gradually worsening eyesight

**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 sweats



Cool, pale skin



Headache



Fast heartbeat



Feeling sick (nausea)





Feeling very hungry



Changes in vision



Feeling sleepy



Feeling 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



Less appetite



Feeling dizzy



Being sick (vomiting)



Stomach pain



Bloating of the stomach



Constipation



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-oesophageal reflux disease'



Gas (flatulence)



Tiredness



Increase of pancreatic enzymes (such as lipase and amylase) shown in blood tests



Headache

### **Uncommon** (may affect up to 1 in 100 people)



Allergic reactions like rash, itching or hives



Change in the way food or drink tastes



Fast pulse



Burping



A delay in the emptying of the stomach



Gallstones



Weight loss

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store. Side effects should also be reported to Novo Nordisk Limited (Telephone Novo Nordisk Customer Care Centre 0800 023 2573). Calls may be monitored for training purposes. By reporting side effects you can help provide more information on the safety of this medicine.

## If you feel sick, here are some tips to help manage it:



### Try to

- Eat smaller portions
- Eat slowly
- Stay hydrated. If you feel sick, drinking cold water can help
- Listen to your body. Stop eating at the first sign of fullness



### Avoid

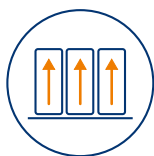
- Fried or fatty foods
- Overly sweet or spicy foods
- Drinking alcohol and fizzy drinks

## Things to remember when using RYBELSUS®:

- It is important to take RYBELSUS® on an empty stomach because any kind of food, beverages, or oral medications may reduce RYBELSUS® entering your bloodstream and taking effect
- Only take RYBELSUS® with a sip of water (up to 120 ml). The effectiveness of RYBELSUS® has not been studied with any other type of drink
- RYBELSUS® may not work properly if you eat, drink, or take other oral medication within 30 minutes of taking RYBELSUS®
- Low blood sugar (hypoglycaemia) can occur with RYBELSUS®, particularly if you are taking a sulfonylurea medicine or insulin with RYBELSUS®. 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

- Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicine to see if they are okay to take with RYBELSUS®

Before you use RYBELSUS® for the first time, your healthcare professional will tell you how to take it. Your doctor will prescribe the strength that is right for you. Do not change your dose unless your doctor has told you to.



## Storage

- Make sure to keep your RYBELSUS® medication out of sight and reach of children
- Do not use your 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 your medicine in the original package in order to protect from light and moisture. This medicine does not require any special temperature storage conditions
- Please refer to your Package Leaflet: Information for the patient enclosed with your medication for more information



# Staying active is a key part of managing diabetes

## Regular activity can help:

- Reduce the risk of additional health problems
- Weight management
- Regulate blood sugar
- Give you more energy

## Even little things can make a big difference

Here are some activities that can help you reach your health goals:



Take the stairs instead of using a lift or escalator



Walk your dog around the neighbourhood



Walk to places in town within a short distance



Mow the lawn or garden



Stretch or practise yoga

Patient organisations, such as Diabetes UK, often have helpful information that can support you.



# Healthy eating habits

Healthy eating habits should be an important part of everyone's life. They are especially important for people with diabetes, since what you eat plays a big part in managing your blood sugar levels.

## Healthy eating choices can help you:

- Manage your blood sugar level
- Reach or maintain a healthy weight
- Reduce the risk of diabetes complications

Keep in mind that it is important to eat a variety of foods. Think of choosing foods that are nourishing, tasty and easy to fit into your lifestyle.



Vegetables



Fruit



Whole grains



Poultry



Fish

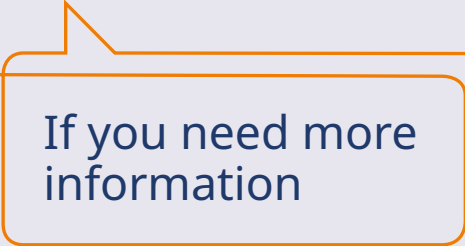
Ask your healthcare professional for more advice on eating habits that can help you with your health goals.



## Useful words to know

Term	Description
Diabetic ketoacidosis	A life-threatening condition. It is caused by the build-up of ketones in the blood when the body breaks down fat instead of glucose due to severe lack of insulin.
GLP-1 (glucagon-like peptide-1)	A hormone primarily produced in the gut, which is released in response to food. It helps the body release insulin which helps manage blood sugar levels. Medication like RYBELSUS® is designed to act like the GLP-1 hormone. You might hear this type of medication referred to as a 'GLP-1' or an incretin.
Glucose	The main type of sugar in the blood. It is also the major energy source for the body.
Hyperglycaemia	When your blood sugar levels are too high.
Hypoglycaemia	When your blood sugar levels are too low (below 4 mmol/l).
Insulin	A hormone produced by an organ in the body called the pancreas. It helps regulate the amount of glucose in your blood.
Retinopathy	Damage to the back of the eyes (the retina) which can cause problems with vision. In diabetes, this can be caused by high blood sugar levels damaging blood vessels to the retina.





## If you need more information

If you have any questions or need anything explaining further, please contact your doctor, local pharmacist or nurse. They will be able to support you with any queries you may have and, if necessary, advise you on who to contact for more information.

[www.novonordisk.co.uk](http://www.novonordisk.co.uk) ↗

Novo Nordisk have been working in diabetes since 1923. To find out more about our work, please visit our website.



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