Regulatory Operations

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Package leaflet: Information for the patient

Rybelsus® 1.5 mg tablets
Rybelsus® 4 mg tablets
Rybelsus® 9 mg tablets

semaglutide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Rybelsus® is and what it is used for
2. What you need to know before you take Rybelsus®
3. How to take Rybelsus®
4. Possible side effects
5. How to store Rybelsus®
6. Contents of the pack and other information

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 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.

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 allergic to semaglutide or any of the other ingredients of this medicine (listed in section 6).

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) 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 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 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; see section 4.

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.

Patients with delayed stomach emptying (gastroparesis)
If you have slow (delayed) stomach emptying (called gastroparesis), use of Rybelsus® may lead to serious or severe gastrointestinal adverse events. Talk to your doctor before using Rybelsus®.

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.

Sudden changes to your eyesight
If you notice a sudden loss of vision or rapidly worsening eyesight during treatment with semaglutide, urgently contact your doctor. This may be caused by a very rare side effect called non-arteritic anterior ischaemic optic neuropathy (NAION) (See section 4: Serious side effects). Your doctor will refer you for an eye examination by an ophthalmologist and you may have to stop treatment with 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.

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 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).

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 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 less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take 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 take
- The starting dose is one 1.5 mg tablet once a day for one month.
- After one month, your doctor will increase your dose to one 4 mg tablet once a day.
- Your doctor will instruct you to stay on a dose for minimum one month before increasing to a higher dose.
- Your doctor may increase your dose to one 9 mg tablet once a day if your blood sugar is not controlled well enough with a dose of 4 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.
- Rybelsus® should always be taken as one tablet per day. You should not take two tablets to get the effect of a higher dose.

Taking this medicine
- Take your Rybelsus® tablet on an empty stomach after a recommended fasting period of at least 8 hours.
- 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 eating, drinking 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).

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

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.

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Rybelsus®
semaglutide

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 (see section 2: "Sudden changes to your 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)
- 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.
- Feeling sick (nausea) – this usually goes away over time
- Diarrhoea – this usually goes away over time

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
- 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-esophageal reflux disease'
- Gas (flatulence)
- Tiredness
- Increase of pancreatic enzymes (such as lipase and amylase) shown in blood tests
- Changed skin sensation
- 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 this leaflet. You can also report side effects directly via

Yellow Card Scheme
Website: https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rybelsus®

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 'EXP'. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light and moisture. This medicine does not require any special temperature storage conditions.

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.

6. Contents of the pack and other information

What Rybelsus® contains
- The active substance is semaglutide. Each tablet contains 1.5, 4 or 9 mg semaglutide.
- The other ingredients are salcaprozate sodium, magnesium stearate. See also section 2, 'Rybelsus® contains sodium'.

What Rybelsus® looks like and contents of the pack

Rybelsus® 1.5 mg tablets are white to light yellow and round (6.5 mm in diameter). They have '1.5' on one side and 'novo' on the other side.
Rybelsus® 4 mg tablets are white to light yellow and round (6.5 mm in diameter). They have '4' on one side and 'novo' on the other side.
Rybelsus® 9 mg tablets are white to light yellow and round (6.5 mm in diameter). They have '9' on one side and 'novo' on the other side.

The 1.5 mg, 4 mg and 9 mg tablets are available in alu/alu blister cards in pack sizes of 10, 30, 60, 90 and 100 tablets.

Not all pack sizes may be marketed in your country.

Marketing Authorisation Holder and Manufacturer
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