

Regulatory Operations

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Package leaflet: Information for the patient
wegovy® 1.5 mg tablets
wegovy® 4 mg tablets
wegovy® 9 mg tablets
wegovy® 25 mg tablets
semaglutide

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using 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 wegovy® is and what it is used for
2. What you need to know before you use wegovy®
3. How to take wegovy®
4. Possible side effects
5. How to store wegovy®
6. Contents of the pack and other information

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wegovy®
semaglutide



1. What wegovy® is and what it is used for

What wegovy® is

wegovy® is a medicine for weight loss and weight maintenance that contains the active substance semaglutide. It is similar to a natural hormone called glucagon-like peptide-1 (GLP-1) that is released from the intestine after a meal. wegovy® works by acting on receptors in the brain that control your appetite, causing you to feel fuller and less hungry and experience less craving for food. This will help you eat less food and reduce your body weight. wegovy® should be used with a reduced calorie meal plan and increased physical activity.

What wegovy® is used for

wegovy® is used for weight loss and weight maintenance in addition to diet and physical activity in adults, who have:

- a BMI of 30 kg/m² or greater (with obesity) or
- a BMI of 27 kg/m² and less than 30 kg/m² (overweight) and weight-related health problems.

BMI (Body Mass Index) is a measure of your weight in relation to your height.

2. What you need to know before you use wegovy®

Do not take wegovy® 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 wegovy® or during treatment if you have:

• **Dehydration**

During treatment with wegovy®, 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.

• **Inflammation of the 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.

• **Diabetes**

wegovy® must not be used as a substitute for insulin.

• **Low blood sugar (hypoglycaemia)**

wegovy® can cause low blood sugar. Please see section 4 for the warning signs of low blood sugar levels.

If you have diabetes and are taking a sulfonylurea or an insulin with wegovy® the risk of getting low blood sugar levels (hypoglycaemia) might increase.

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.

• **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.

• **Sudden changes to your eyesight.**

If you notice a sudden loss of vision or rapidly worsening eyesight during treatment with this medicine, 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 this medicine.

• **Patients with delayed stomach emptying (gastroparesis)**

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

• **Treatment response**

If you do not get the expected response with wegovy® tablets, this may be due to how your body has absorbed the medicine. You should follow the instructions given in section 3 'Taking this medicine' for optimal effect of wegovy® tablets.

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 wegovy®.

Children and adolescents

wegovy® tablet is not recommended in children and adolescents under 18 years as the safety and effectiveness in this age group have not been established.

Other medicines and wegovy®

Tell your doctor, pharmacist or nurse 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 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 wegovy® 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.

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, you have to use contraception 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

wegovy® is unlikely to affect your ability to drive and use machines. Some patients may feel dizzy when taking wegovy® mainly during the first 3 months of treatment (see section 4). If you feel dizzy you should not drive or operate machines until you feel better. If you need any further information, talk to your doctor, pharmacist or nurse.

For diabetics using 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.

Sodium content

The 1.5 mg, 4 mg and 9 mg tablets contain less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'. The 25 mg tablets contain 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 wegovy®

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

How much to take

Your treatment will start at a low dose which will be gradually increased over 4 months of treatment.

- The starting dose is one 1.5 mg tablet once a day for one month.
- Your doctor will instruct you to gradually increase your dose every month until you reach the recommended dose of 25 mg once daily.
- Once you reach the recommended dose of 25 mg, do not increase this dose further.

Usually, you will be told to follow as below:

- **Month 1:** initiate treatment with 1.5 mg once daily.
- **Month 2:** increase the dose to 4 mg once daily.
- **Month 3:** increase the dose to 9 mg once daily.
- **Month 4 and onward:** maintain the dose at 25 mg once daily.

Your doctor will assess your treatment on a regular basis. You should not take two tablets to get the effect of a higher dose.

Taking this medicine

- Take your wegovy® tablet on an empty stomach after a recommended fasting period of at least 8 hours.
- Swallow your wegovy® 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 wegovy® tablet wait at least 30 minutes before eating or drinking or taking other oral medicines. Waiting less than 30 minutes lowers the absorption of semaglutide.

People with type 2 diabetes

Tell your doctor if you have type 2 diabetes. Your doctor may adjust the dose of your diabetes medicines to prevent you from getting low blood sugar.

If you take more wegovy® than you should

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

If you forget to take wegovy®

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

If you stop taking wegovy®

Do not stop using this medicine without talking to your doctor. 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 (diabetic retinopathy). If you have diabetes you should inform your doctor if you experience eye problems, such as changes in vision, during treatment with this medicine.

Uncommon: may affect up to 1 in 100 people

- 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.
- Kidney or bladder stones. Signs may include back or lower abdomen pain, difficulty in urination or change in colour of your urine.

- Rare:** may affect up to 1 in 1,000 people
- Severe allergic reactions (anaphylactic reactions, angioedema).
You should seek immediate medical help and inform your doctor straight away if you get symptoms such as breathing problems, swelling of face, lips, tongue, and/or throat with difficulty swallowing, wheezing, fast heartbeat, pale and cold skin, feeling dizzy or weak
 - Hip fractures.

- 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 to one of your eyes 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

- headache
- feeling sick (nausea)
- being sick (vomiting)
- diarrhoea
- constipation
- stomach pain
- feeling weak or tired
- upset stomach or indigestion.

These usually go away over time.

Common: may affect up to 1 in 10 people

- feeling dizzy
- burping
- gas (flatulence)
- bloating of the stomach
- inflamed stomach ('gastritis') – the signs include stomach ache, feeling sick (nausea) or being sick (vomiting)
- reflux or heartburn – also called 'gastro-oesophageal reflux disease'
- gallstones
- hair loss
- change in the way food or drink tastes
- change in skin sensation
- low blood sugar (hypoglycaemia) in patients with diabetes.

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.

Uncommon: may affect up to 1 in 100 people

- low blood pressure
- feeling dizzy or lightheaded on standing or sitting up because of a drop in blood pressure
- fast heartbeat
- increase of pancreatic enzymes (such as lipase and amylase) shown in blood tests
- a delay in the emptying of the stomach
- low blood sugar (hypoglycaemia) in patients without diabetes
- increased levels of bilirubin in your blood. Signs include jaundice which is yellowing of the skin or the whites of your eyes.

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 the Yellow Card Scheme at: <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 wegovy®

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 wegovy® contains

- The active substance is semaglutide. Each tablet contains 1.5 mg, 4 mg, 9 mg or 25 mg of semaglutide.
- The other ingredients are salcaprozate sodium and magnesium stearate.

What wegovy® looks like and contents of the pack

wegovy® 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.

wegovy® 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.

wegovy® 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.

wegovy® 25 mg tablets are white to light yellow and oval shaped (6.8 mm x 12 mm). They have '25' on one side and 'novo' on the other side.

The 1.5 mg, 4 mg, 9 mg and 25 mg tablets are available in alu/alu blister cards in pack sizes of 10, 30 and 90 tablets.

Not all pack sizes may be marketed in your country.

Marketing Authorisation Holder and Manufacturer

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