

Package leaflet: Information for the patient

wegovy® 7.2 mg solution for injection in pre-filled pen 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 use wegovy®
4. Possible side effects
5. How to store wegovy®
6. Contents of the pack and other information

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

Weight management

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 use 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:

- **Effects on the digestive system**

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 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.

- **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®.

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

The safety and efficacy of wegovy® 7.2 mg has not been studied in children (below 12 years of age) or adolescents (above 12 years of age).

Other medicines and wegovy®

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines.

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

- Warfarin or other similar medicines taken by mouth to reduce blood clotting (oral anti-coagulants). When you start treatment with e.g. warfarin or similar medicines, frequent blood testing to determine the ability of your blood to clot may be required.

Pregnancy and breast-feeding

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, you should stop using this medicine at least two months in advance. If you become or are pregnant, think you may be pregnant or are planning to have a baby when using this medicine, talk to your doctor straight away, as your treatment will need to be stopped.

You should not use this medicine if you are breast-feeding, as it is unknown if it passes into breast milk.

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, 'Warnings 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

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.

3. How to use wegovy®

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

How much to use

Adults

For weight management

Your treatment will start at a low dose which will be gradually increased over 16 weeks of treatment as follows:

- When you first start using wegovy®, the starting dose is 0.25 mg once weekly.
- Your doctor will instruct you to gradually increase your dose every 4 weeks until you reach the dose of 2.4 mg once weekly.

For weight management in patients with obesity

- If needed, a dose increase to the next maintenance dose 7.2 mg once weekly can be made after a minimum of 4 weeks on 2.4 mg.
- The maximum dose is 7.2 mg once weekly.

Usually, you will be told to follow the table below.

For weight management

Dose escalation	Weekly dose
Week 1–4	0.25 mg
Week 5–8	0.5 mg
Week 9–12	1 mg
Week 13–16	1.7 mg
From week 17	2.4 mg
From week 21 – for adult patients with obesity, if needed	7.2 mg

Your doctor will assess your treatment on a regular basis.

How wegovy® is given

wegovy® is given as an injection under the skin (subcutaneous injection). Do not inject it into a vein or muscle.

- The best places to give the injection are the upper arms, stomach or upper legs.

- Before you use the pen for the first time, ask your doctor or nurse how to use it.

Detailed instructions for use are on the other side of this leaflet.

People with diabetes

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

- Do not mix wegovy® up with other medicines that you inject (e.g. insulins).
- Do not use wegovy® in combination with other medicines that contain GLP-1 receptor agonists (such as liraglutide, dulaglutide, exenatide or lixisenatide).

When to use wegovy®

- You should use this medicine once a week and if possible, on the same day each week.
- You can give yourself the injection at any time of the day – regardless of meals.

If necessary, you can change the day of your weekly injection of this medicine as long as it has been at least 3 days since your last injection. After selecting a new dosing day, continue with once a week dosing.

If you use 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 use wegovy®

If you forgot to inject a dose and:

- it is 5 days or less since you should have used wegovy®, use it as soon as you remember. Then inject your next dose as usual on your scheduled day.
- it is more than 5 days since you should have used wegovy®, skip the missed dose. Then inject your next dose as usual on your next scheduled day. Do not take a double dose to make up for a forgotten dose.

If you stop using 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 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.

These usually go away over time.

Common: may affect up to 1 in 10 people

- feeling dizzy
- upset stomach or indigestion
- 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 – may occur more frequently with semaglutide 7.2 mg
- injection site reactions
- change in the way food or drink tastes
- changed skin sensation – this usually goes away over time and may happen more frequently with semaglutide 7.2 mg
- 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 pen label and carton after 'EXP'. The expiry date refers to the last day of that month.

Do not freeze wegovy® and do not use it if it has been frozen.

Always store the pen in the original carton in order to protect from light.

Before opening:

Store in a refrigerator (2°C to 8°C). Keep away from the cooling element.

During use:

wegovy® may be stored unrefrigerated for up to 28 days at a temperature not above 30°C. Discard the pen if it has been exposed to light or temperatures above 30°C, has been out of the refrigerator for more than 28 days, or has been frozen.

Do not use this medicine if you notice that the solution is not clear and colourless.

After use:

The pen is for single use and contains one dose only. Discard pen after use.

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.
- The other ingredients are disodium phosphate dihydrate, sodium chloride, hydrochloric acid/sodium hydroxide (for pH adjustment), water for injections. See also section 2 'wegovy® contains sodium' for information on sodium.

wegovy® 7.2 mg solution for injection

Each pre-filled pen contains 7.2 mg of semaglutide in 0.75 mL (9.6 mg/mL)

What wegovy® looks like and contents of the pack

wegovy® is a clear and colourless solution for injection in a pre-filled disposable pen.

Each pen contains one dose only.

Pack size of 4 pre-filled pens

Marketing Authorisation Holder

Novo Nordisk A/S
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Denmark

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Package leaflet: Information for the patient

wegovy®

7.2 mg

wegovy® 7.2 mg solution for injection in pre-filled pen
semaglutide



Use **wegovy®** one time each week

Pull out to get started



Instructions on how to use **wegovy®** pen

Important information before you start

The package contains one package leaflet and four **wegovy®** pre-filled pens.

This part of the package leaflet instructs on how to use the pen. For further information regarding your medicine please refer to the other side of this package leaflet.

Each pen is only to be used once.

It comes with:

- **one pre-set dose.**
- **a needle cover** that hides the built-in needle before, during and after use.
- **an automatic dosing** mechanism that starts when the needle cover is pressed against your skin as described by your doctor or nurse.

When injecting the dose, a yellow bar will appear in the pen window. Do not lift the pen before the yellow bar has stopped moving. If you do, the automatic dosing will continue, but you may not receive your full dose.

The needle cover will lock when the pen is removed from your skin. You cannot pause the injection and restart it later.

People who are blind or have vision problems should not use **wegovy®** pen without help from a person trained to use **wegovy®**.

Always follow these user instructions and any directions given by your doctor or nurse.

Before use After use

Expiry date

(on the back)

Check that wegovy® has not expired

EXP/ XX/XXXX
Batch: AB1234

Always check you have the correct medicine and dose strength.

7.2 mg

Pen window

Check that wegovy® is clear and colourless. Air bubbles are normal. They do not affect your dose.

Pen window

Check that the yellow bar has stopped moving to make sure you received your full dose

Needle cover

Needle is hidden inside

Needle cover

Locks after use

Pen cap

Remove it just before injecting wegovy®

EXP/ XX/XXXX

Batch: AB1234

7.2 mg

How to use your wegovy[®]

1. Prepare for your injection.

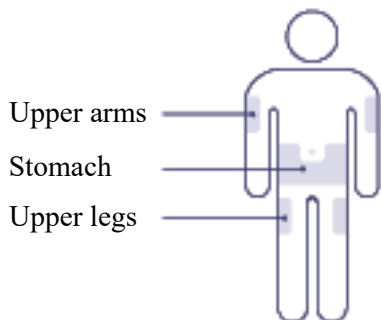
Check your wegovy pen and be careful not to use your pen if:

1. it has expired
2. it appears to have been used or damaged, e.g. if it has been dropped or stored incorrectly
3. the medicine looks cloudy.

Choose your injection site

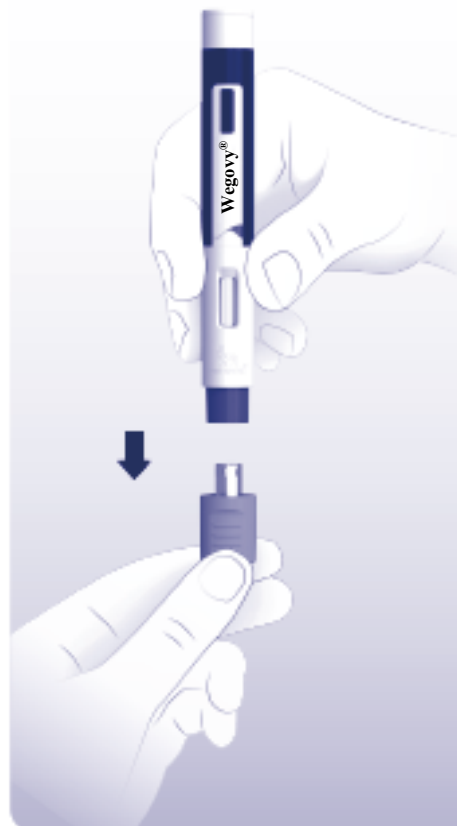
Choose an injection site in one of the body areas marked below. You can choose your upper arms, upper legs or stomach (keep a 5 cm distance from your belly button).

You may inject in the same body area each week, but make sure it is not in the same spot as used the last time.



2. Remove pen cap.

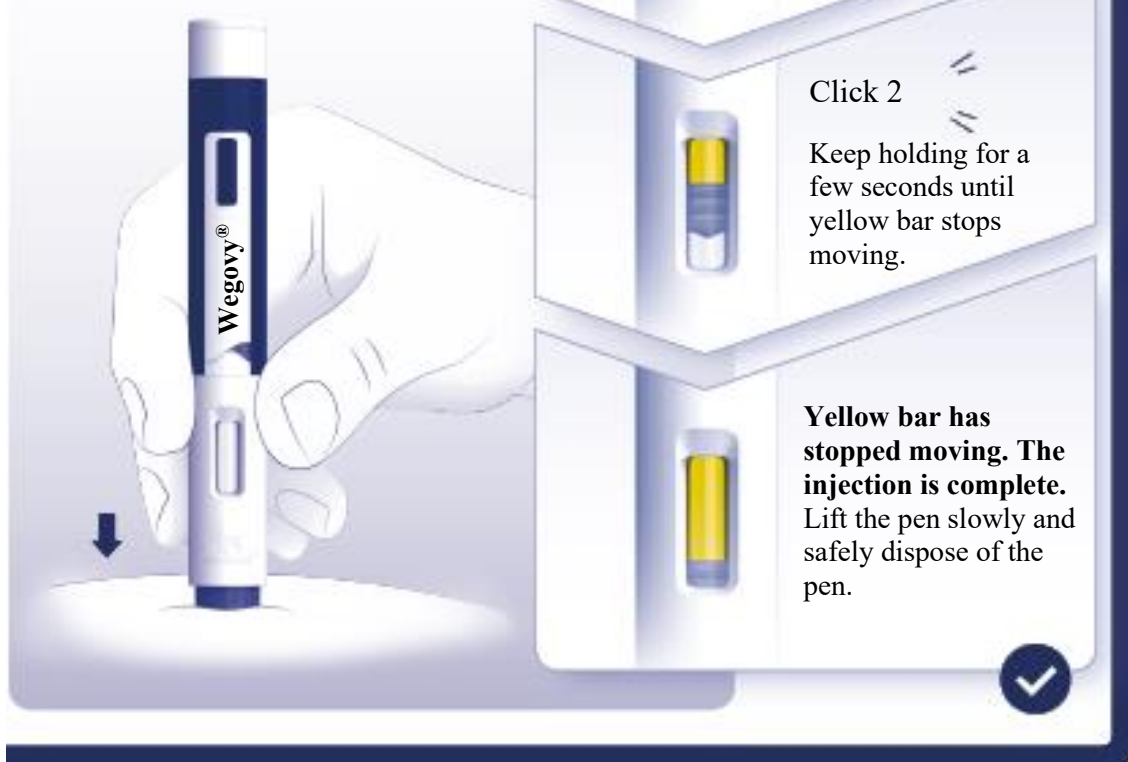
Pull the pen cap straight off your pen.



3. Inject wegovy®

Press the pen firmly against your skin until the yellow bar has stopped moving.

If the yellow bar does not start moving, press the pen more firmly against your skin.



How do I handle my pen safely?

For information regarding your medicine please refer to the other side of this package leaflet.

- The pen is for a single injection of wegovy® under the skin once a week and should be used by one person only.
- Always refer to the instructions on the other side of this package leaflet and ensure you have been shown how to use these pens by your doctor or nurse.
- Always keep wegovy® pens out of sight and reach of children. Also, keep the pen cap away from children to prevent them from swallowing it.
- Treat your pen with care and do not expose it to any kind of liquid. Rough handling or misuse may cause your pen to give less than the full dose or no dose at all.

- Keep the pen cap on until you are ready to inject. Your pen will no longer be sterile if you store an unused pen without the cap, if you pull the pen cap off and put it on again, or if the pen cap is missing. This could lead to an infection.
- Be careful when handling your pen before use and do not touch the needle or the needle cover. The hidden needle can cause needle stick injuries.
- Each pen contains one weekly dose and cannot be reused. Dispose of it after use.

How do I store my unused pens?

For information regarding storage see section 5 on the other side of this package leaflet.

How do I dispose of my pens?

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.