

Package leaflet: Information for the patient

wegovy

0.25 mg, 0.5 mg, 1 mg, 1.7 mg and 2.4 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

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.

wegovy is used together with diet and physical activity for weight management in adolescents ages 12 years and above, who have

- obesity
- body weight >60kg

As an adolescent patient, you should only continue using wegovy if you have lost at least 5% of your BMI after 12 weeks on the 2.4mg dose or maximum tolerated dose (see section 3). Consult your doctor before you continue.

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 severe and on-going pain in the stomach area – see a doctor straight away as this could be a sign of inflamed pancreas (acute pancreatitis).
- **Diabetes**
Do not use wegovy as a substitute for insulin.
- **Low blood sugar (hypoglycaemia)**
Taking a sulfonylurea or an insulin with wegovy might increase the risk of getting low blood sugar levels (hypoglycaemia). Please 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 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.

Children and adolescents

The safety and efficacy of wegovy in children below 12 years of age have not been studied and are not recommended for use in this population.

Other medicines and wegovy

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

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.

Do 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 be extra careful while driving or using machines. If you need any further information, talk to your doctor, pharmacist or nurse.

People with diabetes

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. Avoid driving or using 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

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 wegovy exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

How much to use

Adults

The recommended dose is 2.4 mg once weekly.

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

- 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 recommended dose of 2.4 mg once weekly.
- Once you reach the recommended dose of 2.4 mg, do not increase this dose further.

You will be told to follow the table below.

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

Your doctor will assess your treatment on a regular basis.

Adolescents (above 12 years of age)

For adolescents, the same dose escalation schedule as for adults should be applied (see above). The dose should be increased until 2.4 mg (maintenance dose) or maximum tolerated dose has been reached. Weekly doses higher than 2.4 mg are not recommended.

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 front of your waist (abdomen), your thigh, or your upper arm.
- 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). Signs of inflamed pancreas may include severe and long-lasting pain in your stomach, the pain may move to your back. You should see your doctor immediately if you experience such symptoms.

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.

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
- injection site reactions
- 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

- fast heartbeat
- increase of pancreatic enzymes (such as lipase and amylase) shown in blood tests.

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

Great Britain

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard 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.

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

Store in a refrigerator (2°C – 8°C). Do not freeze. Keep away from the cooling element.

wegovy can be stored out of the refrigerator for up to 21 days at a temperature not above 25°C. The product must not be returned to the refrigerator.

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

After use: Discard 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, sodium hydroxide/hydrochloric acid (for pH adjustment), water for injection.

wegovy 0.25 mg solution for injection

Each pre-filled pen contains 0.25 mg semaglutide in 0.5 mL

wegovy 0.5 mg solution for injection

Each pre-filled pen contains 0.5 mg semaglutide in 0.5 mL

wegovy 1 mg solution for injection

Each pre-filled pen contains 1.0 mg semaglutide in 0.5 mL

wegovy 1.7 mg solution for injection

Each pre-filled pen contains 1.7 mg semaglutide in 0.75 mL

wegovy 2.4 mg solution for injection

Each pre-filled pen contains 2.4 mg of semaglutide in 0.75 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. The pack size of each strength of wegovy contains 4 pre-filled single use pens.

Marketing Authorisation Holder and Manufacturer

Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd
Denmark

This leaflet was last revised in 04/2023

wegovy®

wegovy® comes in five variants:

0.25 mg / 0.5 mL 0.5 mg / 0.5 mL 1 mg / 0.5 mL 1.7 mg / 0.75 mL 2.4 mg / 0.75 mL

This package leaflet applies to all five variants.

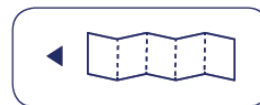
Solution for injection in pre-filled pen
semaglutide



Use wegovy® one time each week



Pull out to get started



Welcome to wegovy

Important information before you start

The package contains one package leaflet and four wegovy pens.

Your 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.
- **automatic dosing** that starts when the needle cover is pressed against your skin as described by your doctor or nurse.

During dosing, 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 without help from a person trained to use wegovy.

Always follow these user instructions and any directions given by your doctor or nurse. Otherwise, it may be harmful to your health.

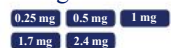
Expiration date

(on the back)

Check that
wegovy® has not
expired



Always check you
have the correct
medication and dose
strength. Either:



Pen window

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

Needle cover

Needle is hidden
inside

Pen cap

Remove it just
before injecting
wegovy®



Pen window

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

Needle cover

locks after use

How to use your wegovy®

1. Prepare for your injection

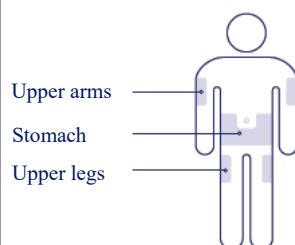
Check your wegovy® pen and be careful not to use your pen if:

- it has expired
- it appears to have been used or damaged, e.g. if it has been dropped or stored incorrectly
- the medication looks cloudy

Choose your injection site

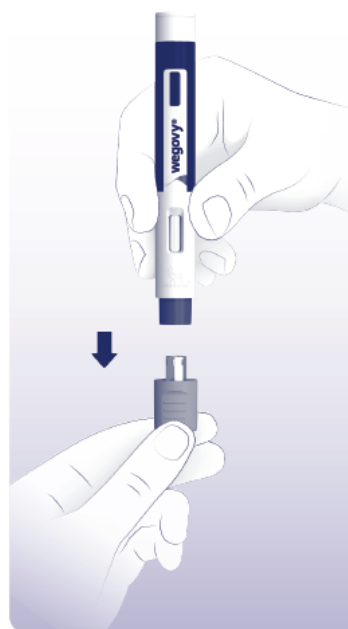
Choose an injection site in one of the body areas marked below. You can choose your upper arms, upper legs, or stomach (keep a 5 cm distance from your belly button).

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?

- 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 reverse side and only use the pen after you have received proper instructions from your doctor or nurse.
- Do not use the pen if the medication has expired, looks cloudy, or if it is the wrong medication or dose strength. It may be harmful to your health. Dispose of it.
- Always keep Wegovy pens and all medicines 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?

- Store unused pens in the original carton until use to protect the medication from light.
- Store your pens in the refrigerator at 2 °C to 8 °C.
- If needed, your pens may be stored at room temperature below 25 °C in the original carton for up to 21 days. The product must not be returned to the refrigerator.
- Do not freeze your pens.
- If your pen has been exposed to light or temperatures above 25 °C, has been out of the refrigerator for more than 21 days, or has been frozen, dispose of it. The medication may have been damaged and could be harmful to your health.



How do I dispose of my pens?

- Dispose of your pens as instructed by your doctor, pharmacist, nurse or local authorities.
- The pen cap and the empty carton can be disposed of in your household trash.
- Do not dispose of pens in your household trash unless permitted by your local authorities.



Manufactured by:
Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd, Denmark

Issued 2021-09
Version: 1

For more information go to wegovy.com

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