

Package leaflet: information for the patient

Wegovy 0.25 mg solution for injection in a pre-filled pen
Wegovy 0.5 mg solution for injection in a pre-filled pen
Wegovy 1 mg solution for injection in a pre-filled pen
Wegovy 1.7 mg solution for injection in a pre-filled pen
Wegovy 2.4 mg solution for injection in a pre-filled pen
semaglutide

This medicine is subject to additional monitoring. This allows new safety information to be identified quickly. You can help by reporting any side effects you may experience. At the end of section 4, you can read how to do this.

Read the entire 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.
- Do you have any questions? Then contact your doctor, pharmacist, or nurse.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm them, even if their symptoms are the same as yours.
- Do you experience any of the side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor, pharmacist, or nurse.

Contents of this leaflet

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1. What is Wegovy and what is it used for?

What is Wegovy?

Wegovy is a weight loss and weight management medication 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 intestines after a meal. It works by acting on sites (receptors) in the brain that regulate your appetite, making you feel full and less hungry, and reducing your desire to eat. This will help you eat less and lose weight. Wegovy can also help prevent heart disease.

What is this medicine used for?

Wegovy is used in combination with diet and exercise to lose weight and maintain weight. It is used in adults with

- a BMI of 30 kg/m² or higher (obesity) or
- a BMI of at least 27 kg/m² but less than 30 kg/m² (overweight) who have weight-related health problems (such as diabetes, high blood pressure, abnormal blood lipid levels, breathing difficulties during sleep called 'obstructive sleep apnea', or a history of heart attack, stroke, or blood vessel problems).

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

Wegovy is used in combination with diet and exercise for weight management in adolescents aged 12 years and older with obesity and body weight > 60 kg.

As a younger patient between 12 and 18 years old, you should only continue using Wegovy if after 12 weeks on the 2.4 mg dose or maximum tolerable dose (see section 3) your BMI has decreased by at least 5%. Contact your doctor before continuing.

2. When should you not use this medicine or be extra careful?

When should you not use this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

When should you be extra careful with this medicine?

Contact your doctor, pharmacist, or nurse before using this medicine.

The use of Wegovy is not recommended if you:

- are using other weight loss products;
- have type 1 diabetes;
- have severely reduced kidney function;
- have severely reduced liver function;
- have severe heart failure;
- have a diabetic eye disease (retinopathy).

There is little experience with Wegovy in patients:

- aged 85 years and older;
- with liver problems;
- with severe stomach or intestinal problems leading to delayed stomach emptying (this is called gastroparesis), or with an inflammatory bowel disease.

Consult your doctor if any of the above apply to you.

If you know you need to undergo surgery where you will be kept under anesthesia (asleep), tell your doctor that you are using Wegovy.

Dehydration

During treatment with Wegovy, you may experience nausea, vomiting, or diarrhea. These side effects can cause dehydration (fluid loss). It is important to drink plenty to prevent dehydration. This is especially important if you have kidney problems. Contact your doctor if you have questions or concerns.

Inflammation of the pancreas

Contact a doctor immediately if you have severe and persistent pain in the abdominal area (see section 4). This may indicate an inflamed pancreas (acute pancreatitis).

People with type 2 diabetes

Wegovy cannot be used as a substitute for insulin. Do not use Wegovy in combination with other medicines that contain GLP-1 receptor agonists (such as liraglutide, dulaglutide, exenatide, or lixisenatide).

Low blood sugar (hypoglycemia)

If you use Wegovy together with a sulfonyleurea or insulin, it may increase the risk of low blood sugar (hypoglycemia). See section 4 for the warning signs of low blood sugar. Your doctor may ask you to monitor your blood sugar levels. This will help your doctor decide whether the dose of the sulfonyleurea or insulin needs to be adjusted to reduce the risk of low blood sugar.

Diabetic eye disease (retinopathy)

If you have an eye disease due to diabetes and use insulin, this medicine may lead to a worsening of your vision and treatment may be necessary. Rapid improvements in blood sugar regulation can lead to a temporary worsening of an eye disease due to diabetes. Contact your doctor if you have a diabetic eye disease and experience eye problems while using this medicine.

Sudden changes in your vision

If you suddenly cannot see or see less during treatment with this medicine, contact your doctor immediately for advice. This may be caused by a very rare side effect called non-arteritic anterior ischemic optic neuropathy (NAION) (see section 4: Serious side effects). Your doctor may refer you for an eye examination and you may need to stop treatment with this medicine.

Children and adolescents under 18 years

The safety and efficacy of Wegovy in children under 12 years have not been studied, it is not recommended to use this medicine in this age group.

Are you using any other medicines?

Are you using other medicines besides Wegovy, have you done so recently, or is there a possibility that you will use other medicines soon? Then tell your doctor, pharmacist, or nurse.

In particular, contact your doctor, pharmacist, or nurse if you are using medicines that contain the following:

warfarin or other oral medicines that lower your blood clotting (oral anticoagulants).

When you start treatment with, for example, warfarin or similar agents, blood tests to test your blood's clotting ability may be necessary more frequently.

Pregnancy and breastfeeding

This medicine should not be used during pregnancy as it is not known if it is harmful to your unborn child. Therefore, it is recommended to use contraception (contraceptives) while using this medicine. If you want to become pregnant, you should stop using this medicine at least two months in advance. Are you pregnant, do you think you might be pregnant, or do you want to become pregnant while using this medicine? Then contact your doctor immediately because your treatment must be stopped.

Do not use this medicine if you are breastfeeding as it is not known 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 using Wegovy, especially during the first 4 months of treatment (see section 4). If you feel dizzy, be extra careful when driving and using machines. For more information, contact your doctor, pharmacist, or nurse.

People with type 2 diabetes

If you use this medicine in combination with a sulfonylurea or insulin, you may experience low blood sugar (hypoglycemia), which can reduce your ability to concentrate. Avoid driving or using machines when you experience symptoms of low blood sugar. See section 2 'When should you be extra careful with this medicine?' for information on an increased risk of low blood sugar and section 4 for warning signs of low blood sugar. Contact your doctor for more information.

Wegovy contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, which means it is essentially 'sodium-free'.

3. How to use this medicine?

Always use this medicine exactly as your doctor has told you. If you are unsure about the correct use, contact your doctor, pharmacist, or nurse.

How much of this medicine should you use?

Adults

The recommended dose is 2.4 mg once a week.

Your treatment will start with a low dose that is gradually increased over 16 weeks of treatment.

When you start using Wegovy, the starting dose is 0.25 mg once a week.

Your doctor will give you instructions to gradually increase your dose every 4 weeks until you reach the recommended dose of 2.4 mg once a week.

Once you have reached the recommended dose of 2.4 mg, you should not increase this dose further.

If you experience significant nausea or vomiting, consult your doctor about delaying the dose increase or reducing to the previous dose until the symptoms subside.

You will usually need to follow the table below.

Dose increase	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 regularly monitor your treatment.

Adolescents (older than 12 years)

For adolescents, the same dose escalation schedule should be applied as for adults (see above). The dose should be increased to 2.4 mg (maintenance dose) or until the maximum tolerable dose is reached. Doses higher than 2.4 mg per week are not recommended.

How is this medicine administered?

Wegovy is administered as a subcutaneous injection. Do not inject it into a vein or muscle.

The best places to give the injection are the front of your upper arm, thighs, or abdomen.

Before using the pen for the first time, have your doctor, pharmacist, or nurse show you how to use the pen.

Detailed instructions on how to use the pen can be found on the other side of this leaflet.

People with type 2 diabetes

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

When do you use this medicine?

Use this medicine once a week, if possible, on the same day each week.

You can inject yourself 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 of this medicine. After selecting a new administration day, administration must continue once a week.

Have you used too much of this medicine?

Contact your doctor immediately. You may experience side effects such as nausea, vomiting, or diarrhea, which can lead to dehydration (fluid loss).

Have you forgotten to use this medicine?

If you forget 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 scheduled day.

Do not use a double dose to make up for a forgotten dose.

If you stop using this medicine

Do not stop using this medicine without discussing it with your doctor.

Do you have any other questions about the use of this medicine? Then contact 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 (affects less than 1 in 10 users)

Complications of eye disease due to diabetes (diabetic retinopathy). If you have diabetes, inform your doctor if you experience eye problems during treatment with this medicine, such as changes in vision.

Uncommon (affects less than 1 in 100 users)

Inflammation of the pancreas (acute pancreatitis). Symptoms of an inflamed pancreas include severe and prolonged pain in your stomach, which may radiate to your back. You should contact your doctor immediately if you experience these symptoms.

Rare (occur in less than 1 in 1,000 users)

Severe allergic reactions (anaphylactic reactions, angioedema). Seek immediate medical help and inform your doctor as soon as possible if you experience symptoms such as difficulty breathing, swelling, lightheadedness, rapid heartbeat, sweating, and loss of consciousness or rapid swelling under the skin in areas such as the face, throat, arms, and legs, which can be life-threatening if the swelling of the throat blocks the airway.

Very rare (occur in less than 1 in 10,000 users)

a medical condition of the eye called non-arteritic anterior ischemic optic neuropathy (NAION) that can cause you to lose vision or see less with one of your eyes without any pain. Contact your doctor immediately if you notice that you suddenly cannot see or gradually see less well (see section 2: 'Sudden changes in your vision').

Not known (cannot be determined from the available data)

Bowel obstruction. A severe form of constipation with symptoms such as abdominal pain, bloating, vomiting, etc.

Other side effects

Very common (occur in more than 1 in 10 users)

headache
nausea
vomiting
diarrhea
constipation
abdominal pain
feeling weak or tired

- these mainly occur during dose increase and usually disappear after some time.

Common (occur in less than 1 in 10 users)

dizziness
stomach complaints or digestive difficulties
belching
gas formation (flatulence or windiness)
bloating in the stomach
inflamed stomach (gastritis) - symptoms include stomach pain, nausea, or vomiting
reflux or heartburn - also known as gastroesophageal reflux disease
gallstones
hair loss

- injection site reactions
- food and drink taste different than usual
- more or less sensation in the skin
- low blood sugar (hypoglycemia) in patients with type 2 diabetes.

The warning signs of low blood sugar can come on suddenly. These can include cold sweat, cool pale skin, headache, rapid heartbeat, nausea or extreme hunger, changes in vision, feeling drowsy or weak, feeling nervous, anxious or confused, difficulty concentrating or trembling. Your doctor will tell you how to treat low blood sugar and what to do if you experience these warning signs.

Low blood sugar is more likely to occur if you are also using a sulfonylurea or insulin. Your doctor may reduce the dose of these medications before you start using this medicine.

Sometimes (occur in less than 1 in 100 users)

- low blood pressure
- dizziness or a light-headed feeling when standing up or sitting down due to a drop in blood pressure
- rapid heartbeat
- increase in pancreatic enzymes (such as lipase and amylase) shown in blood tests
- food remains in the stomach longer than normal (delayed gastric emptying).

Reporting side effects

If you experience side effects, contact your doctor, pharmacist, or nurse. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system as listed in Appendix V. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find it on the label of the pen and on the carton after EXP. It includes a month and a year. The last day of that month is the expiry date.

Store in a refrigerator (2°C – 8°C). Do not freeze. Keep away from the cooling element. Always keep the pen in the original packaging to protect from light. Wegovy can be stored unrefrigerated for up to 28 days at a temperature below 30°C.

Dispose of 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 colorless.

After use: the pen is for single use and contains only one dose. Dispose of the pen after use.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed responsibly and do not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

- The active substance in this medicine is semaglutide.
Wegovy 0.25 mg solution for injection
Each pre-filled pen contains 0.25 mg semaglutide in 0.5 ml (0.5 mg/ml).

Wegovy 0.5 mg solution for injection
Each pre-filled pen contains 0.5 mg semaglutide in 0.5 ml (1 mg/ml).

Wegovy 1 mg solution for injection
Each pre-filled pen contains 1.0 mg semaglutide in 0.5 ml (2 mg/ml).

Wegovy 1.7 mg solution for injection
Each pre-filled pen contains 1.7 mg semaglutide in 0.75 ml (2.27 mg/ml).

Wegovy 2.4 mg solution for injection
Each pre-filled pen contains 2.4 mg semaglutide in 0.75 ml (3.2 mg/ml).
- The other ingredients in this medicine 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 about sodium.

What does Wegovy look like and what is in the package?

Wegovy is a clear and colorless solution for injection in a pre-filled pen for single use.

Each pen contains only one dose.

Pack size of 4 pre-filled pens.

Marketing authorization holder and manufacturer Novo Nordisk A/S

Novo Allé

DK-2880 Bagsværd

Denmark

This leaflet was last approved in

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Other sources of information

More information about this medicine is available on the website of the European Medicines Agency: <http://www.ema.europa.eu>

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1 mg

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2.4 mg

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Semaglutide

Use Wegovy once a week

Instructions for using Wegovy

Important information before you start

The package contains one leaflet and four Wegovy pre-filled pens.

This part of the leaflet is about using the pen. For more information about your medicine, refer to the other side of this leaflet.

Each pen is for single use only.
It comes with:

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

During the injection of the dose, a yellow bar will appear in the pen window. Do not remove the pen from your skin until the yellow bar has stopped moving. If you do, the automatic delivery will continue, but you may not receive your full dose.

The needle shield locks when the pen is removed from your skin. You cannot stop the injection midway and continue later.

People who are blind or have poor vision should not use the Wegovy pen without help from someone trained in using Wegovy.

Always follow these instructions for use and any guidance from your doctor or nurse.

How to use your Wegovy

1. Preparing your injection.

Check your Wegovy pen and ensure you have your pen not used as:

1. the expiration date has passed

2. it appears that the pen has been used or is damaged, for example if it has been dropped or not stored properly
3. the medicine looks cloudy.

Choose your injection site

Choose an injection site on one of the body parts as indicated below. You can choose your upper arms, thighs, or abdomen (keep 5 cm away from your navel).

You can inject into the same body part each week, but make sure not to use the same spot as the previous time

2. Remove the 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 a bit more firmly against your skin.

How do I handle my pen safely?

For information about your medicine, you can refer to the other side of this leaflet.

The pen is for one subcutaneous injection of Wegovy once a week and is for use by one person only.

Always refer to the instructions on the other side of this leaflet and ensure that your doctor or nurse has shown you how to use these pens.

Always keep Wegovy out of the sight and reach of children. Additionally, keep the pen cap away from children to prevent them from swallowing it.

Handle your pen with care and do not expose it to moisture. Rough handling or improper use may result in your pen delivering less than the full dose or no dose at all.

Keep the cap on the pen until you are ready to inject. Your pen is no longer sterile if you store an unused pen without the pen cap, if you remove the pen cap and put it back on, or if the pen cap is missing. This can lead to an infection.

Be careful when handling your pen before use and do not touch the needle or needle shield. The hidden needle can lead to accidental needle sticks.

Each pen contains one weekly dose and cannot be reused. Dispose of it after use.

How do I store my unused pens?

For information on storing the pens, see section 5 on the other side of this leaflet.

How do I dispose of my pens?

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

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