

Wegovy® FlexTouch® Solution for Injection in Pre-filled Pen

Semaglutide [0.25mg/dose (0.68mg/ml), 0.5mg/dose (1.34mg/ml), 1mg/dose (1.34mg/ml), 1.7mg/dose (2.27mg/ml), 2.4mg/dose (3.2mg/ml)]

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1. What Wegovy® is used for

Wegovy® is used together with diet and physical activity for weight loss and to help keep the weight under control. It is used in adults, who have

- a BMI of 30 kg/m² or greater (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 levels of fats in the blood, breathing problems during sleep called 'obstructive sleep apnoea' or a history of heart attack, stroke or blood vessel problems).

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

2. How Wegovy® works

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. It works by acting on targets (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.

3. Before you use Wegovy®

- When you must not use it

Do not use Wegovy®

- if you are allergic to semaglutide or any of the other ingredients of this medicine (listed in section 8).

- Before you start to use it

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Wegovy®.

The use of Wegovy® is not recommended if you:

- use other products for weight loss,
- have type 1 diabetes,
- have severely reduced kidney function,
- have severely reduced liver function,
- have severe heart failure,
- have diabetic eye disease (retinopathy).

There is little experience with Wegovy® in patients:

- of 75 years and older,
- with liver problems,
- with severe stomach or gut problem which results in delayed stomach emptying (called gastroparesis), or if you have an inflammatory bowel disease.

Please consult your doctor if one of the above applies to you.

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®.

• 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 severe and on-going pain in the stomach area (see section 6) – see a doctor straight away as this could be a sign of 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 (hypoglycaemia)

Taking a sulfonylurea or an insulin with Wegovy® might increase the risk of getting low blood sugar levels (hypoglycaemia). Please see section 6 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)

If you have diabetic eye disease and are using insulin, this medicine may lead to a worsening of your vision, and this may require treatment. 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

This medicine is not recommended in children and adolescents under 18 years as the

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safety and effectiveness in this age group have not been established.

- Taking other medicines

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.

4. How to use Wegovy®

- How much to use

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.
- In case you are feeling very bothered by sickness (nausea) or by being sick (vomiting) talk with your doctor about delaying dose escalation or lowering to the previous dose until symptoms have improved.

Usually, 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.

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 upper arm, upper legs or stomach.
- Before you use the pen for the first time, your doctor, pharmacist or nurse will show you how to use it.

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.

- When to use it

- 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.

- How long to use it

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

- If you forget to use it

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 use a double dose to make up for a forgotten dose.

- If you use too much (overdose)

Talk to your doctor straight away. You may get side effects such as feeling sick (nausea), being sick (vomiting) or have diarrhoea, which may cause dehydration (loss of fluids).

5. While you are using it

- Things you must do

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

- Things you must not do

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.

- Things to be careful of

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

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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 4 months of treatment (see section 6). 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 type 2 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 3, 'Warnings and precautions' for information on increased risk of low blood sugar and section 6 for the warning signs of low blood sugar. Talk to your doctor for further information.

Wegovy® contains sodium

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

6. 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 difficulty, swelling, light-headedness, fast 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 throat swelling blocks the airway.

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 are mainly seen during dose escalation and 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
- change in the way food or drink tastes
- change in skin sensation
- low blood sugar (hypoglycaemia) in patients with type 2 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

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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.

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

7. Storage and disposal of Wegovy®

- Storage

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

Before opening

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

During use

You can keep the pen for 6 weeks when stored at a room temperature below 30°C or in a refrigerator (2°C - 8°C) away from the cooling element. Do not freeze Wegovy® and do not use it if it has been frozen.

When you are not using the pen,

keep the pen cap on in order to protect from light.

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

- Disposal

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.

8. Product description

- What it looks like

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

Each pre-filled pen contains four doses only.

Pack size of 1 pre-filled pen and 4 disposable NovoFine® Plus needles.

- Ingredients

- Active ingredient

The active substance is semaglutide.

Wegovy® FlexTouch® 0.25mg/dose (0.68mg/ml) solution for injection in pre-filled pen

Each pre-filled pen contains 1 mg semaglutide in 1.5 mL solution. One mL of solution contains 0.68 mg semaglutide. One pre-filled pen contains 4 doses of 0.25 mg.

Wegovy® FlexTouch® 0.5 mg/dose (1.34mg/ml) solution for injection in pre-filled pen

Each pre-filled pen contains 2 mg semaglutide in 1.5 mL solution. One mL of solution contains 1.34 mg semaglutide. One pre-filled pen contains 4 doses of 0.5 mg.

Wegovy® FlexTouch® 1 mg/dose

(1.34mg/ml) solution for injection in pre-filled pen

Each pre-filled pen contains 4 mg semaglutide in 3 mL solution. One mL of solution contains 1.34 mg semaglutide. One pre-filled pen contains 4 doses of 1 mg.

Wegovy® FlexTouch® 1.7 mg/dose (2.27mg/ml) solution for injection in pre-filled pen

Each pre-filled pen contains 6.8 mg semaglutide in 3 mL solution. One mL of solution contains 2.27 mg semaglutide. One pre-filled pen contains 4 doses of 1.7 mg.

Wegovy® FlexTouch® 2.4 mg/dose (3.2mg/ml) solution for injection in pre-filled pen

Each pre-filled pen contains 9.6 mg semaglutide in 3 mL solution. One mL of solution contains 3.2 mg semaglutide. One pre-filled pen contains 4 doses of 2.4 mg.

- Inactive ingredients

The other ingredients are disodium phosphate dihydrate, propylene glycol, phenol, hydrochloric acid/sodium hydroxide (for pH adjustment), water for injections. See also section 5 Wegovy® contains sodium for information on sodium.

- MAL number

Wegovy® FlexTouch® 0.25 mg/dose (0.68mg/ml) solution for injection in pre-filled pen
MAL24126010AZ

Wegovy® FlexTouch® 0.5 mg/dose (1.34mg/ml) solution for injection in pre-filled pen
MAL24126011AZ

Wegovy® FlexTouch® 1 mg/dose (1.34mg/ml) solution for injection in pre-filled pen
MAL24126012AZ

Wegovy® FlexTouch® 1.7 mg/dose (2.27mg/ml) solution for injection in pre-filled pen
MAL24126013AZ

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Wegovy® FlexTouch® 2.4 mg/dose
(3.2mg/ml) solution for injection in
pre-filled pen
MAL24126014AZ

9. Manufacturer

Manufactured by

Novo Nordisk A/S
Novo Alle 1
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Novo Nordisk A/S
Brennum Park 1
Hilleroed 3400 Denmark

Released by

Novo Nordisk A/S
Novo Alle 1
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10. Product Registration Holder

Novo Nordisk Pharma (Malaysia)
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50470 Kuala Lumpur
Malaysia

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