Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Wegovy® 0.25 mg
Wegovy® 0.5 mg
Wegovy® 1 mg
Wegovy® 1.7 mg
Wegovy® 2.4 mg

Solution for injection in pre-filled pen

Active ingredient

Wegovy 0.25 mg
semaglutide 0.68 mg/ml

Wegovy 0.5 mg
semaglutide 1.34 mg/ml

Wegovy 1 mg
semaglutide 1.34 mg/ml

Wegovy 1.7 mg
semaglutide 2.27 mg/ml

Wegovy 2.4 mg
semaglutide 3.2 mg/ml

Inactive ingredients and allergens in the medicine: See section 2 'Important information about some of this medicine's ingredients' and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Wegovy is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI) of

- ≥ 30 kg/m^2 (obesity), or
- BMI ≥ 27 kg/m^2 to < 30 kg/m^2 (overweight) in the presence of at least one weight-related comorbidity, e.g. impaired blood sugar control (dysglycaemia; prediabetes or type 2 diabetes), hypertension, dyslipidaemia (impaired blood lipid control), obstructive sleep apnoea or cardiovascular disease (disease of the heart and blood vessels)

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

Therapeutic group: Medicines for treatment of diabetes, glucagon-like peptide-1 (GLP-1) analogues.

The active substance semaglutide 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 target proteins (receptors) in the brain that control your appetite, causing you to feel full, less hungry and experience less craving for food. This will help you eat less food and reduce your body weight.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6).

Special warnings about using this medicine

Before treatment with Wegovy, tell your doctor if:

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

Consult your doctor if one of the above applies to you.

- **Dehydration**
  During treatment with Wegovy, you may suffer from nausea, vomiting or 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 4) – see a doctor straight away, as this could be a sign of inflamed pancreas (acute pancreatitis).

- **Patients 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 level (hypoglycaemia)**
  Taking a sulfonylurea or insulin with Wegovy might increase the risk of low blood sugar levels (hypoglycaemia). Please see section 4 for 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 level.

- **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 improvement 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 for children and adolescents under the age of 18 years, as the safety and effectiveness in this age group have not been studied yet.

Drug interactions
If you are taking or have recently taken other medicines, including non prescription medications and dietary supplements, tell your doctor or pharmacist.
In particular, tell your doctor or pharmacist if you are using medicines containing the following:
- warfarin or other similar medicines taken by mouth to reduce blood clotting (oral anticoagulants). When you start treatment with a medicine e.g. warfarin or similar medicines, frequent blood testing to determine the ability of your blood to clot may be required.

Pregnancy and breastfeeding

Pregnancy
This medicine should not be used during pregnancy, as its effect on your unborn child is not known. Therefore, it is recommended to women of childbearing age treated with this medicine to use contraception. If you plan to become pregnant, you should stop using this medicine at least two months before the planned pregnancy. If you become or are pregnant, think you may be pregnant or plan to become pregnant when using this medicine, talk to your doctor straight away, as your treatment with this medicine will need to be stopped.

Breastfeeding
Do not use this medicine if you are breastfeeding, as it is unknown if it passes into breast milk.

Driving and using machines
Wegovy is unlikely to affect (or has a negligible effect) on 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 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.

Patients with type 2 diabetes
If you use this medicine in combination with a sulfonylurea or insulin, low blood sugar level (hypoglycaemia) may occur, which may reduce your ability to concentrate. Avoid driving or using machines if you notice any signs of low blood sugar level. See section 2 ‘Special warnings about using this medicine' for information on increased risk of low blood sugar level and section 4 for warning signs of low blood sugar level. Talk to your doctor for further information.

Important information about some of this medicine’s ingredients
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dosage or about how to inject this medicine. Only your doctor will determine your dosage and how you should inject this medicine. The recommended dosage is usually:
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 the dose further.
- If you are feeling very bothered by nausea or vomiting, talk with your doctor about delaying dose escalation or lowering to the previous dose until the symptoms improve.

Usually, you will be told to follow the table below

Treatment week	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.

Patients 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 developing low blood sugar level.

Do not exceed the recommended dose.

Mode of administration
Wegovy is given as an injection under the skin (subcutaneous injection). Do not inject it into a vein or muscle.

- The best places for injection are the front of the upper arm, upper leg or abdomen.
- Before you use the pen for the first time, your doctor, pharmacist or nurse will show you how to use it.

Detailed instructions on how to use the pen are provided below in this leaflet.

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 at least 3 days have passed since your last injection. After selecting a new injection day, continue with injecting once a week.

If you have accidentally injected a higher dosage
Talk to your doctor straight away. You may experience side effects such as nausea, vomiting or diarrhoea, which may cause dehydration (loss of fluids). If you have injected an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you**.**

If you forgot to inject the medicine at the scheduled time
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 forgotten dose. Then inject your next dose as usual on your next scheduled day.

Do not inject a double dose to make up for a forgotten dose.
Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop treatment with this medicine without consulting your doctor.

If you stop injecting the medicine
Do not stop using this medicine without talking to your doctor.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take a medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects
Like with all medicines, using Wegovy may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Serious side effects
Common (may affect up to 1 in 10 users)
- 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 users)
- Inflamed pancreas (acute pancreatitis). Signs of inflamed pancreas may include severe and long-lasting pain in the abdomen, the pain may move to the back. You should see your doctor immediately if you experience such symptoms.

Rare (may affect up to 1 in 1,000 users)

- Severe allergic reactions (anaphylactic reactions, angioedema). You should seek immediate medical help and inform your doctor straight away if you develop 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 may be life threatening if throat swelling blocks the airway.

Other side effects

Very common side effects (may affect more than 1 in 10 users)
- headache
- nausea
- vomiting
- diarrhoea
- constipation
- abdominal pain
- feeling weak or tired

– These effects have been observed mainly during dose escalation and usually go away over time.

Common side effects (may affect up to 1 in 10 users)
- feeling dizzy
- upset stomach or indigestion
- burping
- gas (flatulence)
- abdominal bloating
- inflamed stomach (gastritis) – the signs include abdominal pain, nausea or vomiting
- reflux or heartburn – also called ‘gastro-oesophageal reflux disease’
- gallstones
- hair loss
- injection site reactions
- low blood sugar level (hypoglycaemia) in patients with type 2 diabetes.

The warning signs of low blood sugar level may appear suddenly. They can include cold sweat, cool pale skin, headache, fast heartbeat, nausea or extreme hunger, 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 level and what to do if you notice these warning signs.
Low blood sugar level is more likely to develop if you also take a sulfonylurea or insulin. Your doctor may reduce the dose of these medicines before you start taking this medicine.

Uncommon side effects (may affect up to 1 in 100 users)
- low blood pressure
- feeling dizzy or lightheaded on standing or sitting up because of a drop in blood pressure
- fast heartbeat
- increase in pancreatic enzymes (such as lipase and amylase) observed in blood tests
- slowing of gastric emptying.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il) which opens an online form for reporting side effects, or you can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the pen label and the package. The expiry date refers to the last day of that month.

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

After opening

- The pen may be stored for 6 weeks at a 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 not in use, store the pen closed with the cap in order to protect from light.

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

Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:
Propylene glycol, phenol, disodium phosphate dihydrate, hydrochloric acid, sodium hydroxide and water for injections.

What the medicine looks like and contents of the pack:
Wegovy 0.25 mg: Each pre-filled pen contains 1 mg semaglutide in 1.5 ml
Wegovy 0.5 mg: Each pre-filled pen contains 2 mg semaglutide in 1.5 ml
Wegovy 1 mg: Each pre-filled pen contains 4 mg semaglutide in 3 ml
Wegovy 1.7 mg: Each pre-filled pen contains 6.8 mg semaglutide in 3 ml
Wegovy 2.4 mg: Each pre-filled pen contains 9.6 mg semaglutide in 3 ml

Wegovy is a clear and colourless solution for injection in a pre-filled pen.
Each pre-filled pen contains 4 doses.

Wegovy 0.25, 0.5, 1, 1.7 and 2.4 mg solution for injection in a pre-filled FlexTouch pen is available in the following pack sizes:
1 pre-filled pen and 4 disposable NovoFine Plus needles.

Registration holder's name and address:

Novo Nordisk Ltd.
1 Atir Yeda St.
Kfar Saba 4464301

Manufacturer's name and address:
Novo Nordisk A/S
Novo Allé, DK-2880 Bagsværd,
Denmark

Revised in October 2023 according to Ministry of Health guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Wegovy 0.25 mg: 172-70-37485
Wegovy 0.5 mg: 172-71-37486
Wegovy 1 mg: 172-72-37487
Wegovy 1.7 mg: 172-73-37488
Wegovy 2.4 mg: 172-74-37489

Wegovy IL PIL OCT 2023–NOTIFICATION

Instructions for use of Wegovy

Before you start using Wegovy pre-filled FlexTouch pen once weekly, **always read these instructions carefully** and talk to your doctor, nurse or pharmacist about how to inject Wegovy correctly.

Wegovy pen is a pen with a dose selector that **contains four of your prescribed doses of Wegovy, corresponding to four times of once-weekly use**.

Please use the designated place in the inner part of the carton pack to keep track of how many injections you have used and how many doses remain in the pen.

Wegovy is marketed in five different pens, each containing one of the following prescribed doses of semaglutide:

0.25 mg 0.5 mg 1 mg 1.7 mg 2.4 mg

Always start by checking your pen label to make sure that it contains your prescribed dose of Wegovy.

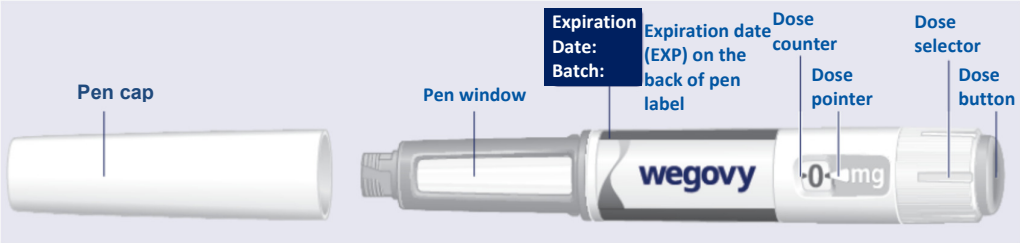
The pen is designed to be used with 30G, 31G, and 32G disposable needles up to a length of 8 mm.

The pack contains:

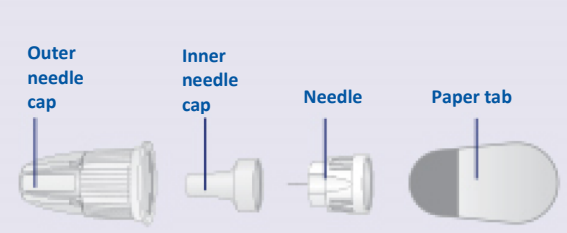
- Wegovy pen
- 4 disposable NovoFine Plus needles
- Patient leaflet

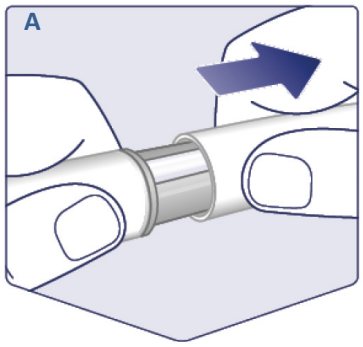
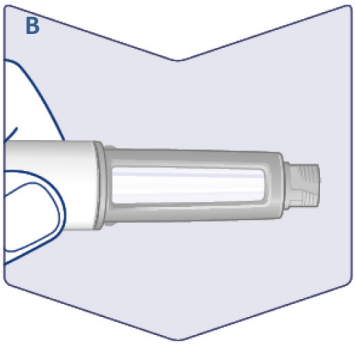
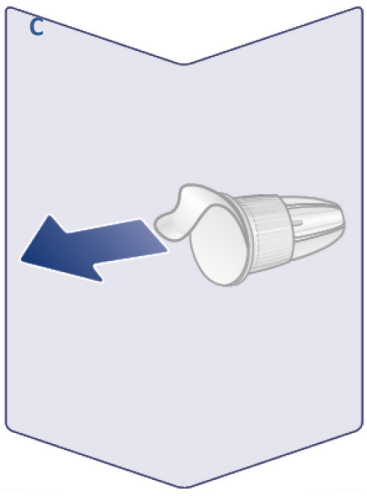
Wegovy FlexTouch pen (example)

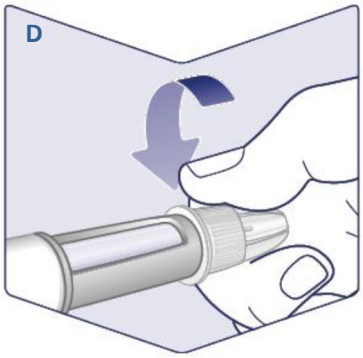
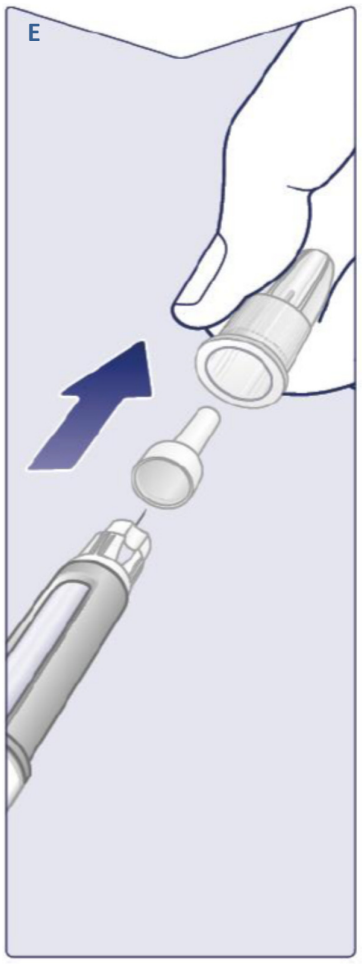
Please note: The pen may differ in size and the pen label may differ in colour from the example shown in the figures. These instructions apply to all Wegovy FlexTouch pens.



NovoFine Plus needle (example)

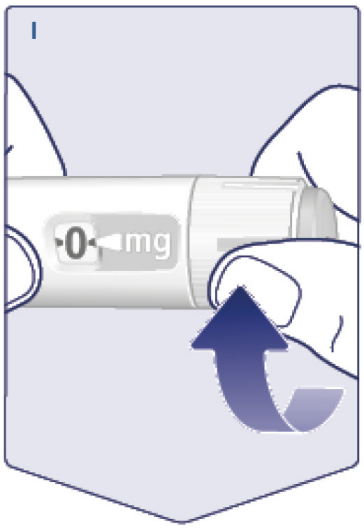
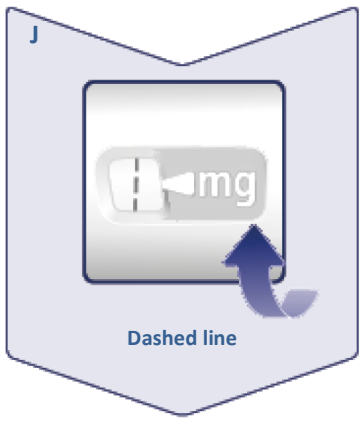
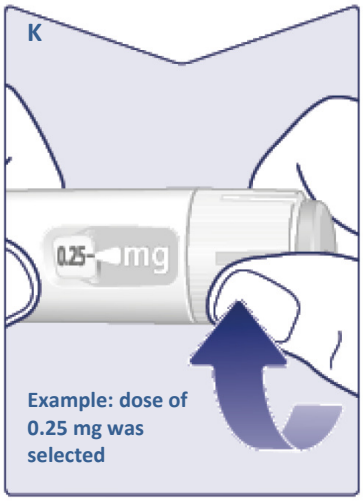


1 Prepare the pen with a new needle	
Check the name and dose of the pen to make sure that it contains your prescribed dose of Wegovy. **Remove the pen cap.** (See figure A).	
Check that the solution in the pen is clear and colourless. Look through the pen window. If Wegovy solution looks cloudy or coloured, do not use the pen. (See figure B).	
Always use a new needle for each injection. **Take a needle** when you are ready to inject. Check the paper tab and the outer needle cap for damages that could impair sterility. If any damage is seen, use a new needle. **Tear off the paper tab.** (See figure C).	

Push the needle straight onto the pen. Turn it until it is tightly attached to the pen. (See figure D).	
The needle is covered by two caps. You must remove both caps. If you forget to remove both caps, you will not inject any Wegovy. **Remove the outer needle cap and keep it for later.** You will need it to safely remove the needle from the pen after the injection. **Remove the inner needle cap and dispose of it.** A drop of Wegovy may appear at the needle tip. You must still check the Wegovy flow if you use a new pen for the first time. See **'Check the flow with each new pen'.** Never use a bent or damaged needle. For more information about needle use, see **'About needles'** below in these instructions. (See figure E).	

Check the flow with each new pen	
If the Wegovy pen is already in use, go to **'2 Select the dose'.** Only check the Wegovy flow before the **first injection with each new pen.** Turn the dose selector until you see the flow check symbol (▪ ▪ ▬). (See figure F).	
Make sure the flow check symbol lines up with the dose pointer. (See figure G).	

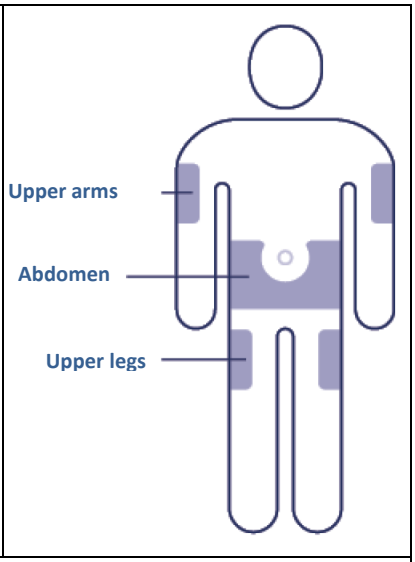
Check the flow	
Hold the pen with the needle pointing up. **Press and hold the dose button** until the dose counter returns to 0. The 0 must line up with the dose pointer. A drop of Wegovy should appear at the needle tip. This drop indicates that the pen is ready for use. If a drop does not appear, check the flow again. **This should only be done twice.** If there is still no drop, **change the needle and check the flow once more.** **Do not use the pen** if a drop of Wegovy still does not appear. (See figure H).	

2 Select the dose	
Turn the dose selector until the **dose counter stops,** and the pen **shows your prescribed dose.** (See figure I).	
The dashed line ( ) in the dose counter will guide you to your dose. The dose selector clicks differently when turned forward, backwards or past your dose. You will hear a 'click' every time you turn the dose selector. Do not set the dose by counting the number of clicks you hear. (See figure J).	
When your prescribed dose lines up with the dose pointer, you have selected your dose. In this figure, the dose 0.25 mg is shown as an example. If the dose counter stops before you reach your prescribed dose, see the section **'Do you have enough Wegovy?'** below in these instructions. (See figure K).	

Choose the injection site

Choose the upper arms, upper legs or abdomen (keep a 5 cm distance from the belly button).

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

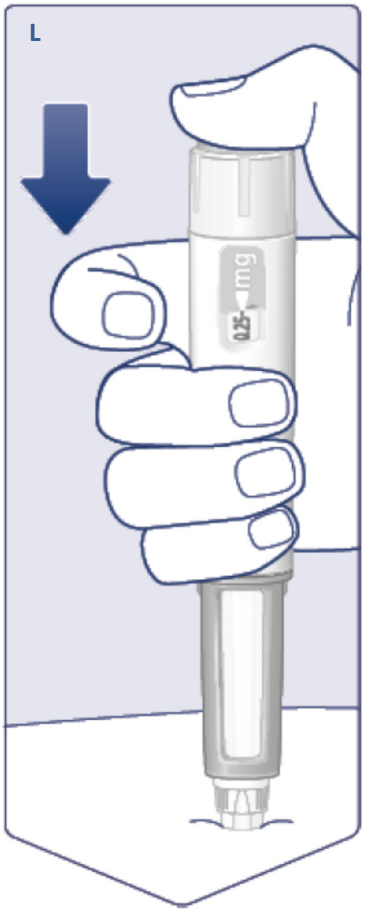


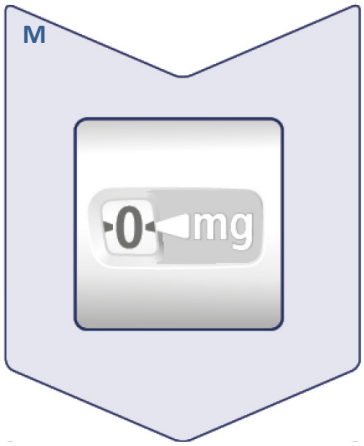
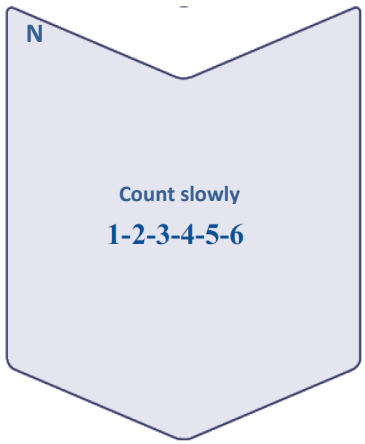
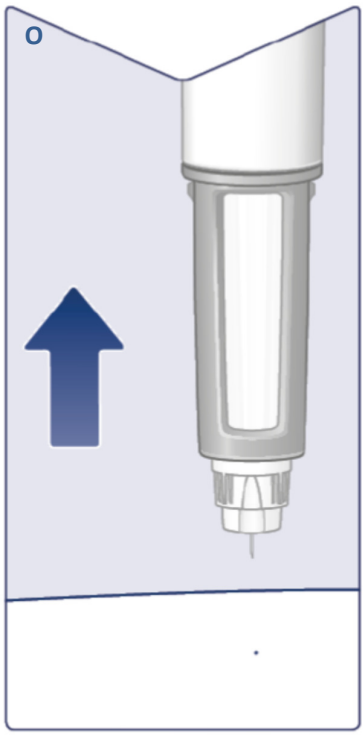
3 Inject the dose

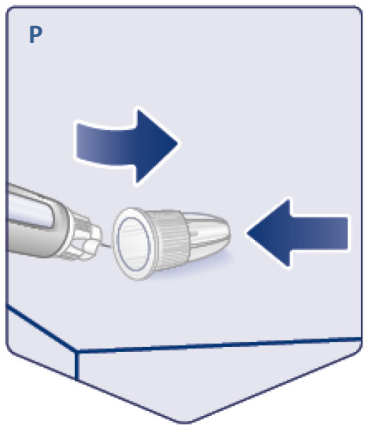
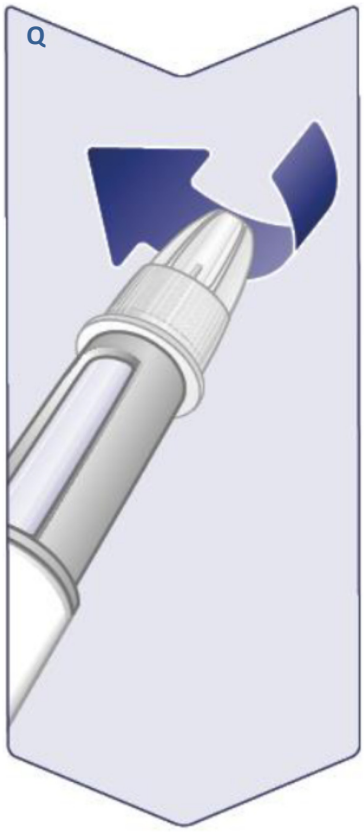
Insert the needle into the skin.

Make sure you can see the dose counter. Do not cover it with your fingers. This could interrupt the injection.

(See figure L).



Press and hold the dose button until the dose counter shows 0. (See figure M). **Keep pressing the dose button with the needle in the skin and slowly count to 6.** The 0 must line up with the dose pointer. You may hear or feel a click when the dose counter returns to 0. (See figure N).	 
Remove the needle from the skin. If the needle is removed too early, a stream of Wegovy may come out from the needle tip and the full dose will not be delivered. If blood appears at the injection site, press lightly on the area to stop the bleeding. You may see a drop of Wegovy at the needle tip after injecting. This is normal and does not affect the injected dose. (See figure O).	

4 After the injection	
Insert the needle tip into the outer needle cap on a flat surface without touching the needle or the outer needle cap. **Once the needle is covered,** carefully push the outer needle cap until the needle is completely covered. (See figure P).	
Unscrew the needle and dispose of it carefully as instructed by your doctor, nurse, pharmacist or local authorities. **Never try to put the inner needle cap back on the needle.** You may stick yourself with the needle. **Always dispose of the needle immediately after each injection** to prevent blocked needles, contamination, infection, and inaccurate dosing. **Never store the pen with the needle attached.** (See figure Q).	

Close the pen with the cap after each use to protect Wegovy from light. (See figure R).	
When the pen is empty, dispose of the pen without a needle attached to it as instructed by your doctor, nurse, pharmacist, or local authorities. The pen cap and the empty carton pack can be disposed of in the household waste.	
About needles	
How to identify a blocked or damaged needle • If 0 does not appear in the dose counter after continuously pressing the dose button, you may have used a blocked or damaged needle. • In this case, you have **not** received any Wegovy – even though the dose counter has moved from the original dose that you have set. **How to handle a blocked needle** • Change the needle as instructed in **'1 Prepare the pen with a new needle'** and go to **'2 Select the dose'**.	

Caring for the pen	
Use the pen with care. Rough handling or misuse may cause inaccurate dosing. If this happens, you might not get the intended effect of Wegovy. • See section 5 in this leaflet to read the storage conditions for the pen. • **Do not inject Wegovy that has been exposed to direct sunlight.** • **Do not subject Wegovy to frost and never inject Wegovy that has been frozen.** Dispose of the pen. • **Do not drop the pen** or knock it against hard surfaces. • **Do not try to refill the pen.** Once empty, it must be disposed of. • **Do not try to repair the pen** or pull it apart. • **Do not expose the pen to dust, dirt or liquid.** • **Do not wash, soak or lubricate the pen.** If necessary, clean it with a mild detergent using a moistened cloth.	
Do you have enough Wegovy?	
If the dose counter stops before you reach your prescribed dose, there is not enough Wegovy left for a full dose. Dispose of the pen and use a new Wegovy pen.	

⚠ Important information

- **Only inject one dose of Wegovy once weekly.** If you do not use Wegovy as prescribed, you may not get the intended effect of this medicine.
- If you use more than one type of injectable medicine, it is **very important to check the name and dose** indicated in the pen label **before use.**
- **Do not use this pen without help if you have poor eyesight and cannot follow these instructions.** Get help from a person with good eyesight who is trained to use the Wegovy pen.
- Always keep the pen and needles **out of sight and reach of others, especially children.**
- **Never share** the pen or needles with other people.
- **Needles are for single use only. Never reuse the needles,** as it may lead to blocked needles, contamination, infection and inaccurate dosing.
- Caregivers must **be very careful when handling used needles** to prevent accidental needle stick injuries and infection.