

Package leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Ozempic® 1 mg
Solution for injection in pre-filled pen

The active ingredient is semaglutide.

**1 ml of solution for injection contains 1.34 mg semaglutide.
semaglutide 1.34 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 all of this leaflet carefully before you use 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?

Ozempic is intended for treating adults with type 2 diabetes whose disease is not well-controlled, in addition to diet and exercise:

- on its own when treatment with metformin is not suitable due to intolerance or contraindication.
- in addition to other medicines for the treatment of diabetes.

Ozempic is given in addition to other diabetes medicines to control your blood sugar levels when the other medicines are not enough on their own. These other medicines include: medicines for diabetes that are taken by mouth (such as metformin, thiazolidinediones, sulfonylureas) or insulin.

Therapeutic group: diabetes medicines, GLP-1 analogs

Ozempic contains the active substance semaglutide. It helps your body reduce your blood sugar level only when blood sugar level is too high, and it can help prevent heart disease. It is important that you continue with your diet and exercise plan as told by your doctor, pharmacist or nurse.

2. Before using this medicine

Do not use Ozempic if:

you are sensitive (allergic) to semaglutide or to any of the other ingredients of this medicine (as listed in section 6 'Additional information').

Special warnings about using this medicine

Talk to your doctor, pharmacist or nurse before using Ozempic.

This medicine is not an insulin and should not be used if:

- you have type 1 diabetes – a condition where your body does not produce any insulin.
- you develop diabetic ketoacidosis – a complication of diabetes with a high level of blood sugar, breathing difficulty, confusion, excessive thirst, a sweet smell to the breath or a sweet or metallic taste in the mouth.

Ozempic is not an insulin and therefore should not be used as a substitute for insulin.

Effects on the digestive system

During treatment with this medicine, you may feel nauseous or vomit or have diarrhea. These side effects can cause dehydration (loss of fluids). It is important that you drink plenty of fluids to prevent dehydration. This is especially important if you have kidney problems. Talk to your doctor if you have any questions or concerns.

Severe and on-going stomach pain which could be due to acute pancreatitis

If you have severe and on-going pain in the stomach area – see a doctor straight away as this could be a sign of acute pancreatitis (inflamed pancreas).

Hypoglycemia

Combining a sulfonylurea or an insulin with this medicine might increase the risk of low blood sugar levels (hypoglycemia). See section 4 for the warning signs of a low blood sugar level. 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 a 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. Tell your doctor if you have diabetic eye disease or if you experience eye problems during treatment with this medicine.

Children and adolescents

This medicine is not intended for children and adolescents under 18 years old. There is no information about the safety and efficacy of using this medicine in children and adolescents.

Examinations and follow-up

Periodic eye examinations should be performed by an ophthalmologist.

Drug interactions

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including nonprescription medicines and dietary supplements. Particularly if you are using medicines containing:

- warfarin or other similar medicines taken by mouth to reduce blood clotting (oral anti-coagulants). Frequent blood testing to determine the ability of your blood to clot may be required.
- if you inject insulin, your doctor will tell you how to reduce the dose of insulin and will advise you to monitor your blood sugar more frequently, in order to prevent hyperglycemia (high blood sugar) and diabetic ketoacidosis (a complication of diabetes that occurs when the body is unable to break down glucose because there is not enough insulin).

Pregnancy, breast-feeding, and fertility

If you are pregnant or breast-feeding, think you might be pregnant, or are planning to have a baby, ask your doctor for advice before taking this medicine.

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 pregnant when using this medicine, talk to your doctor right away, as your treatment will need to be changed.

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

Driving and using machines

If you use this medicine in combination with a sulfonylurea or insulin, low blood sugar level (hypoglycemia) may occur which may reduce your ability to concentrate. Avoid driving or using machines if you get 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 the warning signs of low blood sugar level. Talk to your doctor for further information.

One of the common side effects of this medicine is dizziness which may affect some patients' ability to drive or operate machines.

Important information about some of this medicine's ingredients

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

3. How to use Ozempic

Always use this medicine as your doctor has told you. Check with your doctor or pharmacist if you are not sure about your dosage and about how to take this medicine. Only your doctor will determine your dosage and how you should take this medicine.

The standard dosage is usually:

- The starting dose is 0.25 mg once a week for four weeks.
- After four weeks your doctor will increase your dose to 0.5 mg once a week.
- Your doctor may increase your dose to 1 mg once a week if your blood sugar level is not controlled well enough with a dose of 0.5 mg once a week.

Do not change your dosage unless your doctor has told you to.

Do not exceed the recommended dose.

How Ozempic is given

Ozempic 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 thighs, the front of your waist (abdomen), or the top part of your arm.
- Before you use the pen for the first time, your doctor or nurse will show you how to use it.

Detailed instructions for use are given further down the leaflet.

When to use Ozempic

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

To help you remember to inject this medicine once a week only, it is recommended to note the chosen weekday (e.g. Wednesday) on the carton and to write the date on the carton every time you have injected it.

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 it. After selecting a new dosing day, continue with once a week dosing.

If you have accidentally injected a higher dosage of Ozempic

If you have injected an overdose, or if a child has accidentally taken some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. You may get side effects such as nausea.

If you forget to use Ozempic

If you forgot to inject a dose and:

- it is 5 days or less since you should have used Ozempic, inject 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 Ozempic, skip the missed dose. Then inject your next dose as usual on your scheduled day.

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

Adhere to the treatment as recommended by the doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

If you stop using Ozempic

Do not stop using this medicine without talking to your doctor first. If you stop using it, your blood sugar levels may increase.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Side effects

Like all medicines, Ozempic can 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 side effects: may affect up to 1 in 10 users

- complications of diabetic eye disease (retinopathy) – you should inform your doctor if you experience eye problems, such as changes in vision, during treatment with this medicine.

Uncommon side effects: may affect up to 1 in 100 users

- inflamed pancreas (acute pancreatitis) which could cause severe pain in the stomach and back which does not go away. You should see a doctor immediately if you experience such symptoms.

Rare side effects: 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 get symptoms such as breathing problems, swelling of face, lips, tongue and/or throat with difficulty swallowing and a fast heartbeat.

Other side effects

Very common side effects: may affect more than 1 in 10 users

- feeling nauseous – this usually goes away over time
- diarrhea – this usually goes away over time.

Common side effects: may affect up to 1 in 10 users

- vomiting
- low blood sugar level (hypoglycemia) when this medicine is used with another antidiabetic medicine.

The warning signs of low blood sugar level may come on suddenly. They can include: cold sweat, cool pale skin, headache, fast heartbeat, feeling nauseous 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 level and what to do if you notice these warning signs. Low blood sugar level 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 Ozempic.

- indigestion
- inflamed stomach (gastritis) – the signs include stomach ache, feeling nauseous or vomiting
- reflux or heartburn – also called ‘gastro-esophageal reflux disease’ (GERD)
- stomach pain
- bloating of the stomach
- constipation
- burping
- gall stones
- dizziness
- tiredness
- weight loss
- less appetite
- gas (flatulence)
- increase of pancreatic enzymes (such as lipase and amylase).

Uncommon side effects: may affect up to 1 in 100 users

- change in the way food or drink tastes
- fast pulse
- injection site reactions – such as bruising, pain, irritation, itching and rash
- allergic reactions such as rash, itching or hives.

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.

Reporting of side effects

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

<https://sideeffects.health.gov.il>

5. How to store this medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.

Do not use this medicine after the expiry date (exp. date) which is stated on the pen label and carton. 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. Protect from light.

During use:

- You can keep the pen for 6 weeks when stored at a temperature below 30°C or in a refrigerator (2°C – 8°C) away from the cooling element. Do not freeze Ozempic and do not use medicine that has 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 colorless or almost colorless.

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. Additional information

In addition to the active ingredient this medicine also contains: propylene glycol, phenol, disodium phosphate dihydrate, sodium hydroxide/hydrochloric acid (for pH adjustment), water for injections.

What Ozempic looks like and contents of the pack

Ozempic is a clear and colorless or almost colorless solution for injection in a pre-filled injection pen.

One pen contains 4 mg of semaglutide in 3 ml of solution. Each dose contains of 1 mg of semaglutide in 0.74 ml.

Ozempic 1 mg solution for injection is available in the following pack sizes:

1 pen and 4 disposable NovoFine Plus needles.

3 pens and 12 disposable NovoFine Plus needles.

Not all pack sizes may be marketed.

Registration holder's name and address

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

Manufacturer name and address

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

This leaflet was revised in June 2021 according to MoH guidelines.

Registration number of the medicine in the Ministry of Health National Drug Registry:
162-09-35750

Ozempic 1 IL PIL JUNE2021 - notification

Instructions on how to use Ozempic 1 mg solution for injection in pre-filled pen

Please read these instructions carefully before using your Ozempic pre-filled pen.

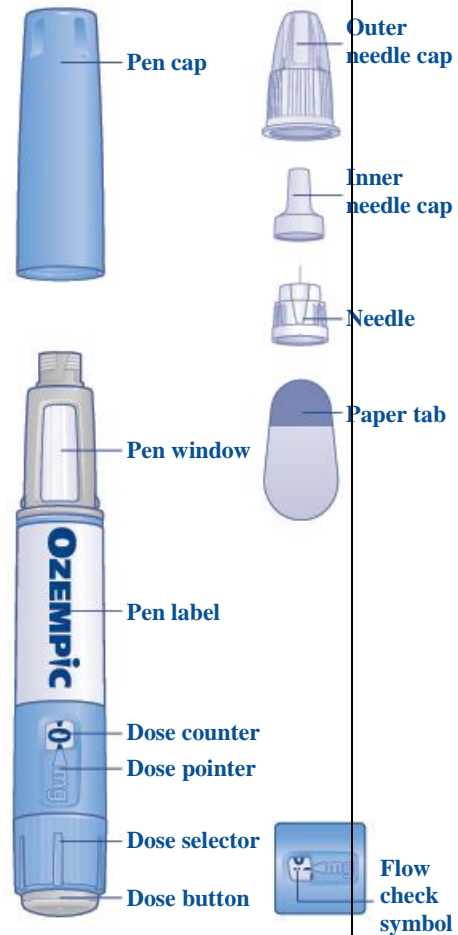
Do not use the pen without proper training from your doctor or nurse. Start by checking your pen to **make sure that it contains Ozempic 1 mg**, then look at the illustrations below to get to know the different parts of your pen and needle.

If you are blind or have poor eyesight and cannot read the dose counter on the pen, do not use this pen without help. Get help from a person with good eyesight who is trained to use the Ozempic pre-filled pen.

Your pen is a pre-filled dial-a-dose pen. It contains 4 mg of semaglutide, and you can only select doses of 1 mg. Your pen is designed to be used with NovoFine and NovoTwist disposable needles up to a length of 8 mm.

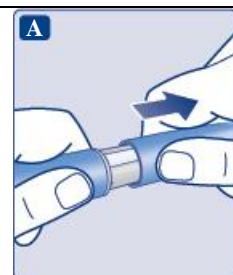
NovoFine Plus needles are included in the pack.

Ozempic® pre-filled pen and needle (example)

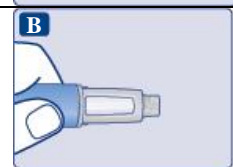


1. Prepare your pen with a new needle

- **Check the name and colored label** of your pen, to make sure that it contains Ozempic. This is especially important if you take more than one type of injectable medicine. Using the wrong medicine could cause severe harm to your health.
- **Pull off the pen cap.**




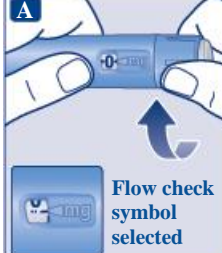



- **Check that the solution in your pen is clear** and colorless. Look through the pen window. If the solution looks cloudy or colored, do not use the pen.



- **Take a new needle**
Check the paper tab and the outer needle cap for damage that could affect sterility. If any damage is seen use a new needle.
 - **Tear off the paper tab.**



<ul style="list-style-type: none"> • Push the needle straight onto the pen. Turn until it is on tight. 	
<ul style="list-style-type: none"> • Pull off the outer needle cap and keep it for later. You will need it after the injection to safely remove the needle from the pen. 	
<ul style="list-style-type: none"> • Pull off the inner needle cap and throw it away. If you try to put it back on, you may accidentally stick yourself with the needle. <p>A drop of solution may appear at the needle tip. This is normal, but you must still check the flow, if you use a new pen for the first time. See step 2 'Check the flow'.</p> <p>Do not attach a new needle to your pen until you are ready to take your injection.</p>	
<p>⚠ Always use a new needle for each injection. This reduces the risk of blocked needles, contamination, infection and inaccurate dosing.</p>	
<p>⚠ Never use a bent or damaged needle.</p>	
<p>2. Check the flow</p>	
<ul style="list-style-type: none"> • Before your first injection with each new pen, check the flow. If your pen is already in use, go to step 3 'Select your dose'. • Turn the dose selector until the dose counter shows the flow check symbol (•• ←). 	
<ul style="list-style-type: none"> • Hold the pen with the needle pointing up. Press and hold in the dose button until the dose counter returns to 0. The 0 must line up with the dose pointer. A drop of solution should appear at the needle tip. 	
<p>A small drop may remain at the needle tip, but it will not be injected. If no drop appears, repeat step 2 'Check the flow' up to 6 times. If there is still no drop, change the needle and repeat step 2 'Check the flow' once more. If a drop still does not appear, dispose of the pen and use a new one.</p>	
<p>⚠ Always make sure that a drop appears at the needle tip before you use a new pen for the first time. This makes sure that the solution flows. If no drop appears, you will not inject any medicine even though the dose counter may move.</p>	

This may indicate a blocked or damaged needle.

If you do not check the flow before your first injection with each new pen, you may not get the prescribed dose and the intended effect of Ozempic.

3. Select your dose

- **Turn the dose selector to select 1 mg.**
Keep turning until the dose counter stops and shows 1 mg.



Only the dose counter and dose pointer will show that 1 mg has been selected.

The dose selector clicks differently when turned forwards, backwards or past 1 mg. Do not count the pen clicks.

⚠ Always use the dose counter and the dose pointer to see that 1 mg has been selected before injecting this medicine.

Do not count the pen clicks.

1 mg in the dose counter must line up precisely with the dose pointer to ensure that you get a correct dose.

How much solution is left?

- **To see how much solution is left**, use the dose counter:
Turn the dose selector until the **dose counter stops**. If it shows 1, there is **at least 1 mg** left in the pen.
If the **dose counter stops before 1 mg**, there is not enough solution for a full 1 mg dose.



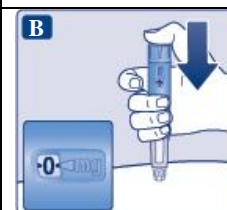
⚠ If there is not enough solution in the pen for a full dose, do not use it. Use a new Ozempic pen.

4. Inject your dose

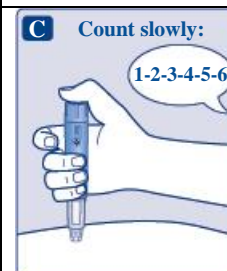
- **Insert the needle into your skin** as your doctor or nurse has shown you.
- **Make sure you can see the dose counter.** Do not cover it with your fingers. This could interrupt the injection.



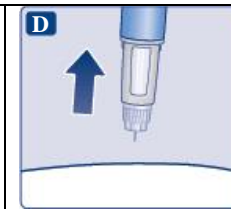
- **Press and hold down the dose button until the dose counter shows 0.** The 0 must line up with the dose pointer. You may then hear or feel a click.



- **Keep the needle in your skin** after the dose counter has returned to 0 and **count slowly to 6.** This is to make sure that you get your full dose.
- If the needle is removed earlier, you may see a stream of solution coming from the needle tip. If so, the full dose will not be delivered.



- **Remove the needle from your skin.** If blood appears at the injection site, press lightly. Do not rub the area.



You may see a drop of solution at the needle tip after injecting. This is normal and does not affect your dose.

- ⚠ **Always watch the dose counter to know how many mg you inject.** Hold the dose button down until the dose counter shows 0.

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 medicine – 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 described in step 5 'After your injection' and repeat all steps starting with step 1 'Prepare your pen with a new needle'. Make sure you select the full dose you need.

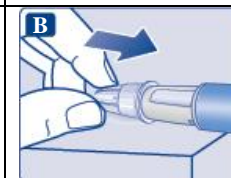
Never touch the dose counter when you inject. This can interrupt the injection.

5. After your injection

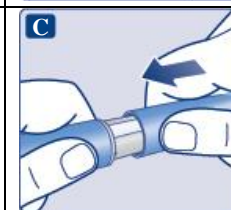
- **Insert the needle tip into the outer needle cap** on a flat surface without touching the needle or the outer needle cap.



- Once the needle is covered, **carefully push the outer needle cap completely on.**
- **Unscrew the needle** and dispose of it carefully in accordance with local guidelines. Ask your doctor, nurse or pharmacist about sharps disposal.



- **Put the pen cap on your pen** after each use to protect the solution from light.



Always dispose of the needle after each injection to ensure convenient injections and prevent blocked needles. If the needle is blocked, you will **not** inject **any** medicine. When the pen is empty, throw it away **without** a needle on 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 remove the needle from your pen immediately after each injection.** This reduces the risk of blocked needles, contamination, infection, leakage of solution and inaccurate dosing.

⚠ **Further important information**

- Always keep your pen and needles **out of the sight and reach of others**, especially children.

- **Never share** your pen or your needles with other people.
- Caregivers must **be very careful when handling used needles** to prevent needle injury and infection.

Caring for your pen

Treat your pen with care. Rough handling or misuse may cause inaccurate dosing. If this happens you might not get the intended effect of this medicine.

- **Do not inject Ozempic which has been frozen.** If you do that, you might not get the intended effect of this medicine.
- **Do not inject Ozempic which has been exposed to direct sunlight.** If you do that, you might not get the intended effect of this medicine.
- **Do not expose your pen to dust, dirt or liquid.**
- **Do not wash, soak or lubricate your pen.** If necessary, clean it with a mild detergent on a moistened cloth.
- **Do not drop your pen** or knock it against hard surfaces. If you drop the pen or suspect a problem, attach a new needle and check the flow before you inject.
- **Do not try to refill your pen.** Throw it away as soon as it is empty.
- **Do not try to repair your pen** or pull it apart.