

Package leaflet: Information for the patient

Ozempic 2 mg solution for injection in a pre-filled pen semaglutide

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? 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 others, even if their symptoms are the same as yours.
- Do you experience any 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 Ozempic and what is it used for?

The active substance in Ozempic is semaglutide. It helps your body lower blood sugar levels, only when blood sugar is too high, and it can help prevent heart disease in patients with type 2 diabetes. It can also help slow the decline of kidney function in patients with type 2 diabetes in a way that goes beyond just lowering blood sugar levels.

Ozempic is used to treat adults (18 years and older) with type 2 diabetes when diet and exercise are not sufficient:

- as a standalone treatment – when you cannot use metformin (another diabetes medicine) or
- with other diabetes medicines – if they are insufficient to control your blood sugar levels. These can be medicines you take orally or inject, such as insulin.

It is important that you continue with your diet and exercise as instructed by your doctor, pharmacist, or nurse.

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.

This medicine is not the same as insulin and you should not use it if:

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

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

If you know you are going to have surgery where you will be under anesthesia (asleep), tell your doctor that you are using Ozempic.

Effects on the digestive system

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

Severe and persistent stomach pain that may be due to acute pancreatitis

Contact your doctor immediately if you have severe and persistent pain in the stomach area. This may indicate acute pancreatitis (inflamed pancreas). See section 4 for warning signs of an inflamed pancreas.

Low blood sugar (hypoglycemia)

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

Diabetic eye disease (retinopathy)

If you have an eye condition due to diabetes and you use insulin, this medicine may worsen your vision, which may require treatment. Inform your doctor if you have a diabetic eye condition or if you experience eye problems during treatment with this medicine. If you have a potentially unstable diabetic eye condition, the use of Ozempic 2 mg is not recommended.

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

This medicine is not recommended for children and adolescents under 18 years because the safety and efficacy in this age group have not yet been established.

Are you taking any other medicines?

Are you taking any other medicines besides Ozempic, have you recently taken any, or might you take any soon? If so, tell your doctor or pharmacist. This also applies to herbal medicines or other medicines you have bought without a prescription.

Tell your doctor, pharmacist, or nurse especially if you are taking medicines that contain any of the following active substances:

Warfarin or other similar oral medicines that counteract blood clotting (oral anticoagulants). Your blood may need to be tested more often to check how quickly it clots.

Or if you are using insulin. Your doctor will tell you how to reduce the insulin dose and will advise you to check your blood sugar more often to prevent hyperglycemia (high blood sugar) and diabetic ketoacidosis (a complication of diabetes that occurs when the body cannot break down glucose because there is insufficient insulin).

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? If so, contact your doctor before using this medicine.

This medicine should not be used during pregnancy as it is not known if it is harmful to the unborn baby. Therefore, the use of contraception is recommended while using this medicine. If you want to become pregnant, discuss with your doctor how the treatment should be adjusted, as you need to stop using this medicine at least 2 months in advance. If you become pregnant while using this medicine, contact your doctor immediately, as your treatment needs to be changed.

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

Driving and using machines

It is unlikely that Ozempic affects your ability to drive and use machines. If you use this medicine in combination with a sulfonylurea or insulin, you may experience low blood sugar (hypoglycemia), which can reduce your concentration. Do not drive or use machines if 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.

Ozempic contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, meaning 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 I use?

The starting dose is 0.25 mg once a week, for four weeks.

After four weeks, your doctor will increase the dose to 0.5 mg once a week.
If your blood sugar level is not adequately controlled with a dose of 0.5 mg once a week, your doctor may advise you to further increase the dose to 1 mg once a week.
If your blood sugar level is not adequately controlled with a dose of 1 mg once a week, your doctor may advise you to further increase the dose to 2 mg once a week.

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

How is this medicine administered?

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

The best places to inject are the front of your thighs, the front of your waist (abdomen), or your upper arm.

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

Detailed instructions for use can be found on the back of this leaflet.

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.

To help you remember to inject this medicine only once a week, it is recommended to note the chosen weekday (for example, a Wednesday) on the box and write the date on the box each time you have injected this medicine.

If necessary, you can change the day of your weekly injection of this medicine, as long as it is at least 3 days after your last injection of this medicine. After selecting a new dosing day, the dosing should continue once a week.

Have you used too much of this medicine?

Contact your doctor immediately if you have used more Ozempic than you should. You may experience side effects such as nausea.

Have you forgotten to use this medicine?

If you forget to inject a dose and:

if it is 5 days or less since you should have used Ozempic, use it as soon as you remember. Then inject your next dose as usual on your scheduled day.

if 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 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. If you stop using it, your blood sugar level may become higher.

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 (may affect less than 1 in 10 users)

complications of diabetic eye disease (retinopathy) – tell your doctor if you experience eye problems such as changes in vision while being treated with this medicine.

Uncommon (may affect less than 1 in 100 users)

inflammation of the pancreas (acute pancreatitis), which can cause severe persistent pain in your abdomen and back. You should contact your doctor immediately if you experience these symptoms.

Rare (may affect less than 1 in 1,000 users)

serious allergic reactions (anaphylactic reactions, angioedema). Seek immediate medical help and inform your doctor as soon as possible if you experience symptoms such as breathing difficulties, swelling of the face, lips, tongue, and/or throat with difficulty swallowing and a rapid heartbeat.

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

a medical condition of the eye called non-arteritic anterior ischemic optic neuropathy (NAION) which can cause you to lose vision in one of your eyes without any pain. Contact your doctor immediately if you notice sudden vision loss or a gradual decrease in vision (see section 2: 'Sudden changes in your vision').

Not known (cannot be estimated 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)

nausea – this usually disappears after some time

diarrhea – this usually disappears after some time

low blood sugar (hypoglycemia), if this medicine is used alongside medicines containing a sulfonylurea derivative or insulin

Common (occur in less than 1 in 10 users)

vomiting

low blood sugar (hypoglycemia), if this medicine is used alongside oral antidiabetic drugs other than sulfonylurea derivatives or insulin

The warning signs of low blood sugar can occur suddenly. These may include: cold sweat, cool pale skin, headache, rapid heartbeat, nausea or feeling very hungry, changes in vision, feeling drowsy or weak, feeling nervous, anxious or confused, having 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 derivative or insulin. Your doctor may reduce the dose of these medicines before you start using this medicine.

- indigestion
- inflamed stomach (gastritis) – symptoms include stomach pain, nausea or vomiting
- reflux or heartburn – also known as gastroesophageal reflux disease (GERD)
- abdominal pain
- bloating in the abdomen
- constipation
- belching
- gallstones
- dizziness
- fatigue
- weight loss
- decreased appetite
- gas formation (flatulence)
- increase in pancreatic enzymeand (such as lipase and amylase)
- headache.

Sometimes (occur in less than 1 in 100 users)

- food or drink tastes different than usual
- rapid heartbeat
- injection site reactions – such as bruising, pain, irritation, itching, and rash
- allergic reactions such as rash, itching, or hives
- food stays 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 mentioned 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 will 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.

Before first use:

Store in a refrigerator (2°C–8°C). Do not freeze. Keep away from the cooling element. Keep the pen cap on the pen to protect it from light.

After first use:

If you store the pen below 30°C or in the refrigerator (2°C–8°C) (not near the cooling element), you can keep it for 6 weeks. Do not freeze Ozempic. If the medicine has been frozen, it must not be used.

Store the pen with the pen cap on when not in use to protect it from light.

Do not use this medicine if you notice that the solution is not clear and colorless or almost colorless.

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. One ml of solution for injection contains 2.68 mg of semaglutide. A pre-filled pen contains 8 mg of semaglutide in 3 ml of solution. Each dose contains 2 mg of semaglutide in 0.74 ml.

The other substances in this medicine are: disodium phosphate dihydrate, propylene glycol, phenol, water for injections, hydrochloric acid/sodium hydroxide (for pH adjustment). See also section 2, 'Ozempic contains sodium'.

What does Ozempic look like and what is in the packaging?

Ozempic is a clear and colorless or almost colorless solution for injection in a pre-filled pen. Each pre-filled pen contains 3 ml of solution, intended for 4 doses of 2 mg.

Ozempic 2 mg solution for injection is available in the following pack sizes:

1 pen and 4 NovoFine Plus disposable needles.

3 pens and 12 NovoFine Plus disposable needles.

Not all pack sizes may be marketed.

Marketing authorization holder and manufacturer

Novo Nordisk A/S

Novo Allé

DK-2880 Bagsværd

Denmark

This leaflet was last approved in

Other sources of information

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

Instructions for use

Ozempic 2 mg solution for injection in a pre-filled pen semaglutide

Instructions for using Ozempic 2 mg solution for injection in a pre-filled pen

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

Discuss with your doctor, nurse, or pharmacist how to correctly inject Ozempic.

Start by checking your pen to ensure it contains Ozempic 2 mg. Then view the images below to familiarize yourself with the different parts of your pen and needle.

If you are blind or have poor vision and cannot read the dose counter on the pen, do not use this pen without help. Seek assistance from a person with good vision who knows how to use the Ozempic pre-filled pen.

Your pen is a pre-filled pen with a rotatable dose selector. The pen contains 8 mg of semaglutide and you can only select doses of 2 mg. One unused pen contains four doses of 2 mg.

Use the table on the inside of the box lid to keep track of how many injections you have had and when you have given the injections.

Your pen is designed for use with 30G, 31G, and 32G disposable needles with a maximum length of 8 mm.

NovoFine Plus needles are included in the package.

Important information

Pay extra attention to these notes as they are important for the safe use of the pen.

1. Fitting your pen with a new needle

Check the name and the colored label of your pen to make sure it contains Ozempic 2 mg. This is especially important if you use more than one type of injectable medication. Using the wrong medication can be harmful to your health.
Remove the pen cap from the pen.

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

Take a new needle.

Check the paper cover and the outer needle cap for damage, as this can affect sterility. Use a new needle if any damage is visible.

Remove the paper cover.

Ensure that you attach the needle correctly.

Press the needle straight onto the pen.

Screw it on.

There is a needle cap and needle shield on the needle. You must remove both. If you do not remove both, you will not inject any solution.

Remove the outer needle cap and keep it for later use. You will need it after the injection to safely remove the needle from the pen.

Remove the inner needle cap and discard it. If you try to put it back, you might accidentally prick yourself with the needle.

A drop of solution may appear at the needle tip. This is normal, but you should still check the flow when using a new pen for the first time. See step 2 'Check the flow with each new pen'.

Only attach a new needle to the pen when you are ready to administer the injection.

Always use a new needle for each injection.

This can prevent clogged needles, contamination, infection, solution leakage, and inaccurate dosing.

Never use a bent or damaged needle.

2. Check the flow with each new pen

If your pen is already in use, proceed to step 3 'Setting your dose'. Check the flow only before your first injection with each new pen.

Turn the dose selector to the flow check mark (** =) directly after '0'. Ensure the flow check mark aligns with the dose pointer.

Hold the pen with the needle pointing upwards.

Press the dose button and hold it until the dose window returns to '0'. The number '0' should align with the dose pointer. A drop of solution should now appear at the needle tip.

Always check for a drop at the needle tip before using a new pen for the first time. This ensures the solution is flowing. If no drop appears, you are not injecting any medication, even if another number appears in the dose window. This may indicate a clogged or damaged needle. If you do not check the flow before each first injection with a new pen, you may not receive the prescribed dose and the intended effect of Ozempic may not occur.

3. Setting your dose drop appears, do not inject any medication, even if a different number appears in the dose display window. This may indicate a clogged or damaged needle. If you do not check the flow before each first injection with a new pen, you may not receive the prescribed dose and the intended effect of Ozempic may not occur.

3. Setting your dose

Turn to the dose setting knob to set to 2 mg.

Keep turning until the dose display window stops and shows 2 mg.

Only the dose display window and the dose indicator arrow indicate that 2 mg is set.

You can only set 2 mg per dose. If your pen contains less than 2 mg, the dose display window stops before 1 is displayed.

The dose setting knob makes a different clicking sound when turned forward, backward, or past 2 mg. Do not count the number of clicks of the pen. Always use the dose display window and the dose indicator arrow before injecting this medicine to

see that 2 mg is set. Do not count the number of clicks of the pen. Only doses of 2 mg are allowed. 2 mg are set with the dose setting knob. 2 mg must be exactly aligned with the dose pointer to ensure you receive the correct dose.

To see how much solution is left, use the dose display window: turn the dose setting button until the dose display window stops.

If 2 is displayed, then there is at least 2 mg left in your pen.

If the dose display window stops before it shows 2 mg, there is not enough solution left for a full dose of 2 mg.

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

4. Injecting your dose

Insert the needle into your skin as shown by your doctor or nurse.

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

Press the administration button and hold it down.

Watch the dose display window return to '0'. The number '0' must be aligned with the dose pointer. You may hear or feel a click.

Keep pressing the administration button while holding the needle in your skin..

Slowly count to 6 while holding down the administration button.

If the needle is removed from the skin earlier, you may see a stream of solution coming from the needle tip. In that case, the full dose has not been injected.

Remove the needle from your skin. You can then release the administration button.

If the injection site starts to bleed, press gently on it.

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

Always keep looking at the dose display window so you know how many mg you are injecting. Keep the administration button pressed until the dose display window returns to '0'.

How to recognize a clogged or damaged needle

- If, after continuously pressing the administration button, the dose display window does not return to '0', you may have used a clogged or damaged needle.
- In that case, you have not received any medication, even if the number in the dose display window has changed compared to the dose you originally set.

What to do with a clogged needle

Replace the needle as described in step 5 'After your injection' and repeat all steps from step 1 'Fitting your pen with a new needle'. Make sure you set the full dose you need.

Do not touch the dose display window during injection. This can interrupt the injection.

5. After your injection

Always remove the needle after each injection and dispose of it for ease of injection and to prevent a clogged needle. If the needle is clogged, no medication will be injected.

Place the outer needle cap on a flat surface and guide the needle tip into it, without touching the needle or cap with your fingers.

Once the needle is covered, gently press the outer needle cap fully onto the needle. Unscrew the needle and dispose of it carefully as instructed by your doctor, nurse, pharmacist, or local authorities.

Replace the pen cap on your pen after each use to protect the solution from light.

If the pen is empty, dispose of it without a needle according to the instructions of your doctor, nurse, pharmacist, or local authorities.

Never attempt to put the inner needle cap back on the needle. You could prick yourself with the needle.

Always immediately remove the needle from your pen after each injection.

This can prevent clogged needles, contamination, infection, solution leakage, and inaccurate dosing.

Other important information

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

Never share your pen or needles with other people.

Caregivers must be very careful when handling used needles to prevent needlestick injuries and cross-contamination.

Maintaining your pen

Handle your pen with the necessary care. Rough handling or improper use can cause inaccurate dosing. In that case, the intended effect of this medication may not occur.

Do not leave the pen in a car or any other place where it can be too hot or too cold.

Do not inject Ozempic that has been frozen. If you do, the intended effect of this medication may not occur.

Do not inject Ozempic that has been exposed to direct sunlight. If you do, the intended effect of this medication may not occur.

Do not expose your pen to dust, dirt, or moisture.

Do not wash, immerse, or lubricate your pen. The pen can be cleaned with a mild dishwashing detergent on a damp cloth.

Do not drop your pen or bump it against a hard surface. If you drop the pen or suspect a problem, you should attach a new needle and check the flow before injecting.

Do not try to refill your pen.

Do not attempt to repair or disassemble your pen.

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