

Ozempic®

semaglutide (rys) 0.25 mg, 0.5 mg/dose

Consumer Medicine Information

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

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This leaflet answers some common questions about Ozempic®.

It does not contain all the available information. It does not take the place of talking to your doctor, diabetes education nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Ozempic® against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Ozempic® is used for

Ozempic® contains the active ingredient semaglutide. This belongs to a group of medicines called ‘GLP-1 receptor agonists’. Ozempic® is an injection that is used once a week.

Ozempic® is used to lower blood sugar (glucose) in adults with type 2 diabetes mellitus.

Diabetes mellitus is a condition where your pancreas does not produce enough insulin to control the level of sugar in your blood or, your body is not able to use the insulin it makes properly.

Ozempic® helps your body to produce more insulin when your blood sugar level is high.

Ozempic® is used on its own if your blood sugar is not properly controlled by diet and exercise alone. Ozempic® is also able to be used with other medicines for diabetes when they are not enough to control your blood sugar levels. These medicines may include oral antidiabetics (such as metformin, thiazolidinedione medicines (TZD's), sulfonylurea medicines) or insulin.

It is important that you keep following any diet and lifestyle advice from your doctor, diabetes education nurse or pharmacist while using Ozempic®.

Ozempic® has not been studied in children and should not be used in children or adolescents under 18 years.

Ozempic® is not addictive.

Ozempic® is available only with a doctor's prescription.

Ask your doctor, diabetes education nurse or pharmacist if you have any questions about why Ozempic® has been prescribed for you.

Before you use Ozempic®

When you must not use it

Do not use Ozempic® if you are allergic (hypersensitive) to semaglutide or to any of the ingredients listed in the “Ingredients” section at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- redness, swelling, rash and itching at the injection site
- rash, itching or hives on the skin
- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body.

If you are not sure whether you should start using this medicine, talk to your doctor.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to use it

Tell your doctor if:

- you are also taking a sulfonylurea (such as glimepiride or glibenclamide) or insulin. Your doctor may tell you to test your blood sugar levels. This will help your doctor to decide if the dose of the sulfonylurea or insulin needs to be changed to avoid you getting hypoglycaemia (low blood sugar).

- you have a history of diabetic retinopathy.
- you have a history of gallstones.

Drink plenty of fluids to avoid dehydration if you experience vomiting or diarrhoea when beginning treatment with Ozempic®.

Dehydration can lead to kidney problems, particularly in patients who have pre-existing kidney disease.

If you notice your urine changes appearance or you produce urine less frequently, see your doctor. Contact your doctor if you have any questions or concerns.

Ozempic® should not be used if you have type 1 diabetes or diabetic ketoacidosis (a complication of diabetes that happens when the body is not able to break down glucose because there is not enough insulin). Ozempic® is not an insulin.

If you experience symptoms of acute pancreatitis, like persistent, severe abdominal pain, you should consult your doctor.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant. Ozempic® should not be used during pregnancy and for at least two months before a planned pregnancy because Ozempic® may harm your unborn child. If you could become pregnant while using Ozempic®, it is recommended to use contraception.

Tell your doctor if you are breast-feeding or plan to breast-feed.

It is not known if Ozempic® passes into breast milk. Do not use Ozempic® if you are breast-feeding.

If you have not told your doctor about any of the above, tell them before you use Ozempic®.

Taking other medicines

Tell your doctor, pharmacist or diabetes education nurse if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket, naturopath or health food shop.

In particular, tell your doctor if you are using medicines containing any of the following active ingredients:

- A sulfonylurea (such as glimepiride or glibenclamide), and/or insulin. This is because using Ozempic® at the same time may cause your blood sugar level to become too low (hypoglycaemia or a “hypo”).
 - When you first start using these medicines together, your doctor may tell you to lower the dose of the sulfonylurea or insulin.
 - If you are also taking a sulfonylurea and/or insulin together with Ozempic®, your doctor may ask you to test your blood sugar levels to begin with. This will help your doctor to decide if the dose of the sulfonylurea and/or insulin needs to be changed.

Tell your doctor about any other medicines that you are taking.

This is very important. Your doctor will advise you if it is all right to keep taking them or if you should stop taking them.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use Ozempic®

Your doctor, diabetes education nurse or pharmacist will have given you advice on how to use your medicine.

Carefully follow all the directions.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor, diabetes education nurse or pharmacist for help.

Ozempic® is supplied as a pre-filled pens containing 1.5 mL or 3 mL of semaglutide solution. The Ozempic® pen containing 1.5 mL can deliver doses of 0.25 mg or 0.5 mg. The Ozempic® pen containing 3 mL delivers doses of 1 mg.

How much to use

Your doctor or diabetes education nurse will tell you how much of this medicine you need to use.

- When you first start using Ozempic®, the starting dose is 0.25 mg once a week for four weeks.
- After four weeks you should increase your dose to 0.5 mg once a week. **Talk to your doctor before increasing your dose.**
- Your doctor may increase your dose to 1 mg if your blood sugar is not controlled well enough with a dose of 0.5 mg once a week.
- **Do not change your dose unless your doctor has told you to.** Any change in dose should be made cautiously and only under medical supervision.

When to use it

You should use Ozempic® 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 Ozempic® once a week only, it is recommended to note the chosen weekday (e.g. Wednesday) on the carton. You can also write the date on the carton every time you have injected Ozempic®.

If necessary you can change the day of your weekly injection of Ozempic® as long as it has been at least 3 days since your last injection of Ozempic®.

How to use it

- Inject Ozempic® under the skin (subcutaneous injection) as shown to you by your doctor or diabetes education nurse. **Never inject Ozempic® into a vein or muscle.**
- Ozempic® may be injected into the front of your waist (abdomen), the front of your thigh, or your upper arm.
- Before you use the pen for the first time, your doctor or diabetes

education nurse will show you how to use it.

Checking your Ozempic[®] pen:

Ozempic[®] should be clear and colourless, or almost colourless.

Do not use this medicine if it is thickened, coloured, or has solid bits in it.

Ozempic[®] should not be used if it has been frozen.

Read the instructions printed later in this leaflet carefully in order to prepare and handle your Ozempic[®] pen correctly.

How long to use it

Do not stop using Ozempic[®] unless your doctor tells you to. If you stop using it, your blood sugar levels may increase.

If you use too much (overdose)

If you use more Ozempic[®] than you should, talk to your doctor straight away. You may get side effects such as a feeling sick (nausea) or being sick (vomiting), or diarrhoea. You may need medical treatment.

If you forget to use it

If you forget a dose and:

- 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 schedule 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 an extra dose or increase the dose to make up for a missed dose.

If you are not sure what to do, talk to your doctor, diabetes education nurse or pharmacist.

While you are using Ozempic[®]

Things you must do

Make sure all your friends, relatives, workmates or carers know that you have diabetes.

Tell your doctor if you often have hypos (low blood sugar levels).

When Ozempic[®] is used with a sulfonylurea (such as glimepiride or glibenclamide) or with insulin, hypos can occur. The dose of your sulfonylurea or insulin may need to be reduced while you take Ozempic[®].

If you experience any of the symptoms of a hypo, immediately eat some sugary food or have a sugary drink, e.g. lollies, biscuits or fruit juice.

Tell your doctor, diabetes education nurse or pharmacist if you are travelling.

Ask them for a letter explaining why you are taking injecting devices with you. Each country you visit will need to see this letter, so you should take several copies.

You may not be able to get Ozempic[®] in the country you are visiting.

Your doctor, diabetes education nurse or pharmacist can provide you with some helpful information.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Ozempic[®].

Things you must not do

Do not stop using your medicine unless your doctor tells you to. If you stop using it, your blood sugar levels may increase.

Do not use this medicine if you think it has been frozen or exposed to excessive heat. It will not work as well.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not share your pen or needles with anyone else.

Things to be careful of

Low blood sugar (hypoglycaemia) may affect your ability to concentrate. Avoid driving or using machines if you get any signs of low blood sugar, including dizziness. Talk to your doctor for further information.

Side effects

Tell your doctor, diabetes education nurse or pharmacist as soon as possible if you do not feel well while you are using Ozempic[®].

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor, diabetes education nurse or pharmacist to answer any questions you may have.

The most common side effects when using Ozempic[®] are diarrhoea and nausea. These side effects are usually mild and normally decrease with continued use.

Tell your doctor if you notice any of the following and they worry you:

- decreased appetite
- headache
- vomiting (being sick)
- indigestion (dyspepsia)
- burping, wind (flatulence) or constipation
- heartburn
- painful or swollen stomach (abdomen)
- blocked or runny nose, sneezing, cough and/or sore throat (upper respiratory tract infection)
- injection site reactions (such as bruising, pain, irritation, itching and rash)
- fast heart beat
- feeling tired
- feeling dizzy
- changes to your vision or eyesight
- unpleasant, abnormal or altered taste sensation
- increase in pancreas blood test results
- low blood sugar (a hypo).

Hypos are more likely to occur if you are also taking a sulfonylurea (such as glimepiride or glibenclamide) or

insulin. A hypo may come on suddenly. The warning signs of a hypo can include:

- cold sweat, cool pale skin
- headache
- feeling sick
- feeling very hungry
- changes in vision
- feeling sleepy, feeling weak
- feeling nervous or anxious, shaking (tremor), fast heart beat
- feeling confused, difficulty concentrating.

Your doctor can provide you with further information about how to treat low blood sugar levels and what to do if you notice these warning signs. If you are already taking a sulfonylurea or insulin, your doctor may reduce the dose of these medicines before you start using Ozempic®.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor if you experience:

- gallstones
- inflamed gall bladder.

When initiating treatment with Ozempic®, you may in some cases experience dehydration as a result of vomiting, nausea or diarrhoea. It is important to avoid dehydration by drinking plenty of fluids.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- severe and persistent pain in the abdomen (stomach area) which might reach through to your back, as well as nausea and vomiting. These can be symptoms of acute pancreatitis. Pancreatitis can be a serious, potentially life-threatening medical condition.
- an allergic reaction. Some symptoms may include:
 - skin rashes over a large part of the body
 - shortness of breath, wheezing
 - swelling of the face, lips or tongue
 - fast pulse

- sweating.

This list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare or very rare. **Tell your doctor if you notice anything else that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

Ask your doctor, diabetes education nurse or pharmacist to answer any questions you have.

After using Ozempic®

Storage

Before opening:

Keep your unopened Ozempic® pens in a refrigerator (2°C to 8°C). Keep away from the cooling element. Do not freeze.

During use:

While you are using your Ozempic® pen you can keep it for 6 weeks *either* at room temperature (not above 30°C), *or* in a refrigerator (2°C to 8°C), away from the cooling element. Do not freeze.

Discard the Ozempic® pen you are using after 6 weeks even if there is still some medicine left in it.

The medicine in Ozempic® must not be frozen, or exposed to heat or direct sunlight. When you are not using the pen, keep the pen cap on in order to protect from light. Never use Ozempic® after the expiry date (EXP) printed on the pen label and carton. The expiry date refers to the last day of that month.

Never use Ozempic® if the solution is not clear and colourless, or almost colourless.

Keep out of the reach of children.

Disposal

Dispose of used needles safely into a yellow plastic sharps container.

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Ozempic® is supplied as a clear, colourless, or almost colourless solution for injection in a pre-filled pen. Each pen contains 1.5 mL of solution, delivering doses of 0.25 mg or 0.5 mg.

One mL solution for injection contains 1.34 mg semaglutide.

One pre-filled pen contains 2 mg semaglutide.

Ozempic® 0.25 mg, 0.5 mg/dose is available in a pack containing 1 pen and 6 disposable NovoFine® Plus needles.

Ingredients

Ozempic® contains semaglutide (rys) 1.34 mg/mL as the active ingredient. The abbreviation “rys” indicates the method of genetic engineering used to manufacture semaglutide.

Ozempic® also contains the following inactive ingredients:

- dibasic sodium phosphate dihydrate
- propylene glycol
- phenol
- hydrochloric acid
- sodium hydroxide
- water for injections.

Sponsor

Ozempic® is supplied in Australia by:

Novo Nordisk Pharmaceuticals Pty. Ltd.

Level 3

21 Solent Circuit

Baulkham Hills NSW 2153

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Australian Registration Number:
AUST R 308324

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Further information

For further information call the NovoCare® Customer Care Centre on 1800 668 626.

www.novonordisk.com.au

You can also get more information about diabetes from Diabetes Australia:

freecall helpline 1300 136 588

www.diabetesaustralia.com.au

The 'Product Information' document is available from the following websites:

www.novonordisk.com.au

<https://www.ebs.tga.gov.au/>

Ozempic®

semaglutide (rys), 0.25 mg or 0.5 mg/dose solution for injection pre-filled pen

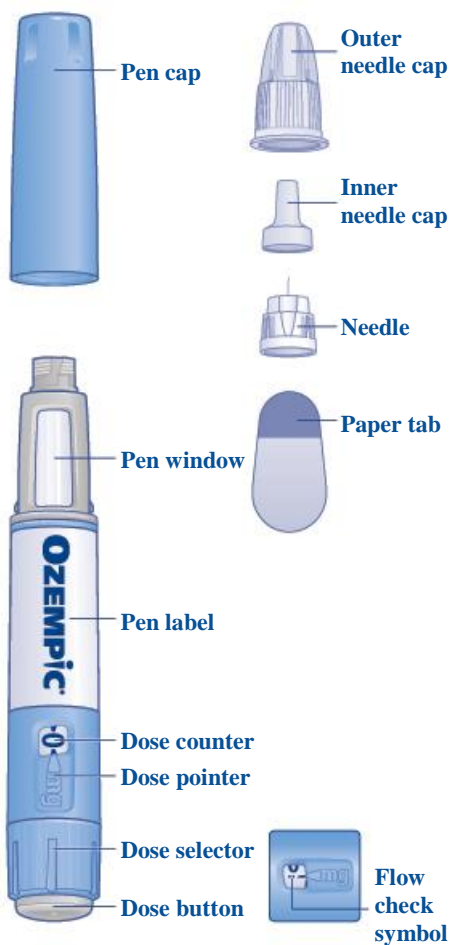
Instructions For Use

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® 0.25 mg, 0.5 mg/dose**, then look at the illustrations below to get to know the different parts of your pen and needle.

Ozempic® pre-filled pen and needle (example)



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 2 mg of semaglutide, and you can select doses of 0.25 mg or 0.5 mg. Your pen is designed to be used with NovoFine® disposable needles up to a length of 8 mm.

NovoFine® Plus needles are included in the pack.

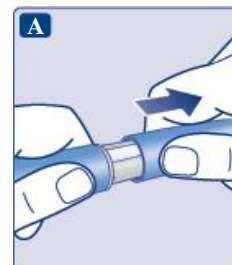
Important information

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

1. Prepare your pen with a new needle

Check the name and coloured label of your pen to make sure that it contains Ozempic® 0.25 mg, 0.5 mg/dose. This is especially important if you take more than one type of injectable medicine. Using the wrong medicine could be harmful to your health.

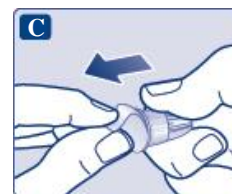
A. Pull off the pen cap.



B. Check that the solution in your pen is clear and colourless. Look through the pen window. If the solution looks cloudy or coloured, do not use the pen.



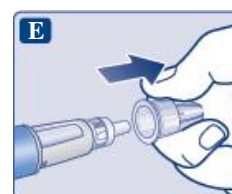
C. Take a new needle and tear off the paper tab. If the paper tab is broken, do not use the needle, as sterility is not guaranteed.



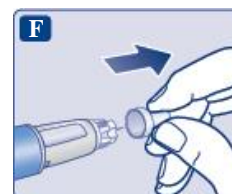
D. Push the needle straight onto the pen. Turn until it is on tight.



E. 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.



F. 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.



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.

Do not attach a new needle to your pen until you are ready to take your injection.

⚠ Always use a new needle for each injection.

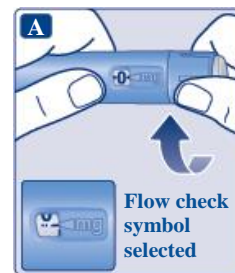
This may prevent blocked needles, contamination, infection and inaccurate dosing.

⚠ Never use a bent or damaged the needle.

2. Check the flow

A. 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** (●●—).



B. 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 solution should appear at the needle tip.



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.

⚠ 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. **This may indicate a blocked or damaged needle.**

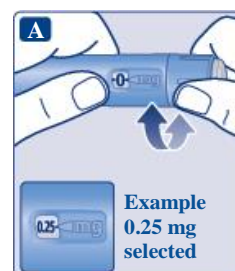
If you do not check the flow before your first injection with each new pen, you may not get the prescribed dose and the intended effect of Ozempic®.

3. Select your dose

A. Turn the dose selector until the dose counter shows your dose (0.25 mg or 0.5 mg).

If you select the wrong dose, you can turn the dose selector forwards or backwards to the correct dose.

The pen can dial up to a maximum of 0.5 mg.



The dose selector changes the dose. Only the dose counter and dose pointer will show how many mg you select per dose.

You can select up to 0.5 mg per dose. When your pen contains less than 0.5 mg, the dose counter stops before 0.5 mg is shown. The dose selector clicks differently when turned forwards, backwards or past the number of mg left. Do not count the pen clicks.

⚠ Always use the dose counter and the dose pointer to see how many mg you have selected before injecting this medicine.

Do not count the pen clicks.

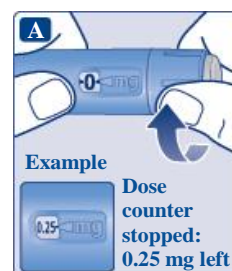
Only doses of 0.25 mg or 0.5 mg must be selected with the dose selector. The selected dose must line up precisely with the dose pointer to ensure that you get a correct dose.

How much solution is left

A. To see how much solution is left, use the dose counter: Turn the dose selector until the **dose counter stops**.

If it shows 0.5, **at least 0.5 mg** is left in your pen.

If the **dose counter stops before 0.5 mg**, there is not enough solution left for a full dose of 0.5 mg.



⚠ If there is not enough solution left in your pen for a full dose, do not use it. Use a new Ozempic[®] pen.

4. Inject your dose

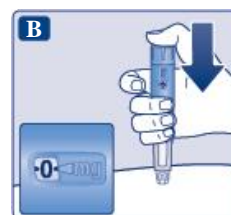
A. Insert the needle into your skin as your doctor or nurse has shown you.

Make sure you can see the dose counter.

Do not cover it with your fingers. This could interrupt the injection.

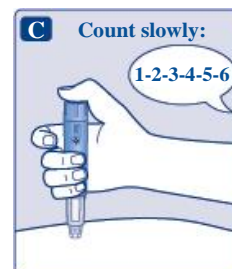


B. Press and hold down the dose button until the dose counter shows 0. The 0 must line up with the dose pointer. You may then hear or feel a click.

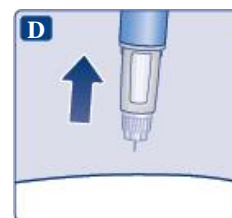


C. Keep the needle in your skin after the dose counter has returned to 0 and **count slowly to 6.**

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.



D. 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.

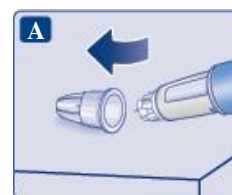
How to handle a blocked needle

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 that you select the full dose you need.

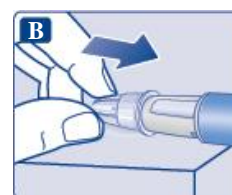
Never touch the dose counter when you inject. This can interrupt the injection.

5. After your injection

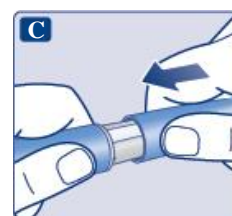
A. Lead the needle tip into the outer needle cap on a flat surface without touching the needle or the outer needle cap.



B. Once the needle is covered, carefully push the outer needle cap completely on.
Unscrew the needle and dispose of it carefully.



C. 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 or pharmacist.

⚠ **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 may prevent 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 cross-infection.

Caring for your pen

Treat your pen with care. Rough handling or misuse may cause inaccurate dosing, which may lead to high blood sugar levels or abdominal discomfort such as nausea or vomiting.

Do not leave the pen in a car or another place where it can get too hot or too cold.

Do not inject Ozempic® which has been frozen. If you do that, your blood sugar level may get too high or you might feel abdominal discomfort such as nausea or vomiting.

Do not inject Ozempic® which has been exposed to direct sunlight. If you do that, your blood sugar level may get too high.

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 it or suspect a problem, attach a new needle and check the flow before you inject.

Do not try to refill your pen. Once empty, it must be disposed of.

Do not try to repair your pen or pull it apart.