Package leaflet: Information for the patient

Ozempic® 2 mg
Solution for injection in pre-filled pen
semaglutide

Read all of this 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.
– If you have any further questions, ask your doctor, pharmacist or nurse.
– This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
– If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ozempic® is and what it is used for
2. What you need to know before you use Ozempic®
3. How to use Ozempic®
4. Possible side effects
5. How to store Ozempic®
6. Contents of the pack and other information

1. What Ozempic® is and what it is used for

Ozempic® contains the active substance semaglutide. It helps your body reduce your blood sugar level only when blood sugar is too high and can help prevent heart disease in patients with type 2 diabetes mellitus (T2DM). It also helps to slow down deterioration of kidney function in patients with T2DM by a mechanism beyond blood glucose lowering.

Ozempic® is used to treat adults (aged 18 years and older) with type 2 diabetes when diet and exercise is not enough:
- on its own – when you cannot use metformin (another diabetes medicine) or
- with other medicines for diabetes – when they are not enough to control your blood sugar levels. These may be medicines you take by mouth or inject such as insulin.

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

2. What you need to know before you use Ozempic®

Do not use Ozempic®
- if you are allergic to semaglutide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to 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 any insulin

- you develop diabetic ketoacidosis – a complication of diabetes with high 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 should therefore not be used as a substitute for insulin.

If you know that you are due to have surgery where you will be under anaesthesia (sleeping), please tell your doctor that you are taking Ozempic®.

Stomach and gut problems and dehydration
During treatment with this medicine, you may feel sick (nausea) or be sick (vomiting), or have diarrhoea. These side effects can cause dehydration (loss of fluids). It is important that you drink 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 ever had pancreatitis (inflammation of the pancreas) which may cause severe pain in the stomach and back which does not go away; see section 4.

Low blood sugar (hypoglycaemia)
Combining a sulfonylurea or an insulin with this medicine might increase the risk of getting low blood sugar levels (hypoglycaemia). Please see section 4 for the warning signs of low blood sugar levels. Your doctor may ask you to test your blood sugar levels. This will help your doctor decide if the dose of the sulfonylurea or insulin needs to be changed to reduce the risk of low blood sugar.

Diabetic eye disease (retinopathy)
If you have diabetic eye disease and are using insulin, this medicine may lead to a worsening of your vision, and this may require treatment. Tell your doctor if you have diabetic eye disease or if you experience eye problems during treatment with this medicine. In case you have potentially unstable diabetic eye disease, it is not recommended that you use Ozempic® 2 mg.

Sudden changes to your eyesight
If you notice a sudden loss of vision or rapidly worsening eyesight during treatment with semaglutide, urgently contact your doctor. This may be caused by a very rare side effect called non-arteritic anterior ischaemic optic neuropathy (NAION) (See section 4: Serious side effects). Your doctor will refer you for an eye examination by an ophthalmologist and you may have to stop treatment with semaglutide.

Patients with delayed stomach emptying (gastroparesis)
If you have slow (delayed) stomach emptying (called gastroparesis), use of Ozempic® may lead to serious or severe gastrointestinal adverse events. Talk to your doctor before using Ozempic®.

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

Other medicines and Ozempic®
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including herbal medicines or other medicines you bought without a prescription.

In particular, tell your doctor, pharmacist or nurse if you are using medicines containing any of the following:
- Warfarin or other similar medicines taken by mouth to reduce blood clotting (oral anti-coagulants). You may need frequent blood tests to check how quickly your blood clots.
- If you are using insulin, your doctor will tell you how to reduce the dose of insulin and will recommend you to monitor your blood sugar more frequently, in order to avoid hyperglycaemia

(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 and breast-feeding
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 affects an unborn baby. Therefore, use of contraception is recommended while using this medicine. If you wish to become pregnant, discuss how to change your treatment with your doctor as you should stop using this medicine at least 2 months in advance. If you become pregnant while 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
Ozempic® is unlikely to affect your ability to drive and use machines. If you use this medicine in combination with a sulfonylurea or insulin, low blood sugar (hypoglycaemia) may occur which may reduce your ability to concentrate. Do not drive or use machines if you get any signs of low blood sugar. See section 2, 'Warnings and precautions' for information on increased risk of low blood sugar and section 4 for the warning signs of low blood sugar. Talk to your doctor for further information.

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

3. How to use Ozempic®

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

How much to use
- 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 is not controlled well enough with a dose of 0.5 mg once a week.
- Your doctor may increase your dose to 2 mg once a week if your blood sugar is not controlled well enough with a dose of 1 mg once a week.

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

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 your upper 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 on the other side of this package 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 use more Ozempic® than you should
If you use more Ozempic® than you should, talk to your doctor straight away. You may get side effects such as feeling sick (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®, 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 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 Ozempic®
Do not stop using this medicine without talking to your doctor. If you stop using it, your blood sugar levels may increase.

If you have any further questions on the use of this medicine, ask 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 up to 1 in 10 people)
- Complications of diabetic eye disease (retinopathy) – you should tell your doctor if you get eye problems, such as changes in vision, during treatment with this medicine.

Uncommon (may affect up to 1 in 100 people)
- Inflamed pancreas (acute pancreatitis) which could cause severe pain in the stomach and back which does not go away. This is a serious, potentially life-threatening condition. You should see a doctor immediately if you experience such symptoms.
  Stop using this medicine and seek urgent medical help if you experience: Severe, persistent pain in the stomach area (abdomen), with or without nausea and vomiting. This could be a sign of acute pancreatitis, which is serious and potentially life-threatening.

Rare (may affect up to 1 in 1 000 people)
- Severe allergic reactions (anaphylactic reactions, angioedema). You must get 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.

Very Rare (may affect up to 1 in 10 000 people)
- A medical condition of the eye called non-arteritic anterior ischaemic optic neuropathy (NAION), which may cause loss of vision without any pain. You should urgently contact your doctor if you notice sudden or gradually worsening eyesight (see section 2: “Sudden changes to your eyesight”).

Not known (frequency cannot be estimated from the available data)
- Bowel obstruction. A severe form of constipation with additional symptoms such as stomach ache, bloating, vomiting etc.

Other side effects

Very common (may affect more than 1 in 10 people)
- Feeling sick (nausea) – this usually goes away over time
- Diarrhoea – this usually goes away over time
- Low blood sugar (hypoglycaemia) when this medicine is used with medicines that contain a sulfonylurea or insulin.

Common (may affect up to 1 in 10 people)
- Being sick (vomiting)
- Low blood sugar (hypoglycaemia) when this medicine is used with oral diabetes medicine other than sulfonylurea or insulin

The warning signs of low blood sugar may come on suddenly. They can include: cold sweat, cool pale skin, headache, fast heartbeat, feeling sick (nausea) or very hungry, changes in vision, feeling sleepy or weak, feeling nervous, anxious or confused, difficulty concentrating or shaking.
Your doctor will tell you how to treat low blood sugar and what to do if you notice these warning signs.
Low blood sugar is more likely to happen if you also take a sulfonylurea or insulin. Your doctor may reduce your dose of these medicines before you start using this medicine.

- Indigestion
- Inflamed stomach ('gastritis') – the signs include stomach ache, feeling sick (nausea) or being sick (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)
- Headache.

Uncommon (may affect up to 1 in 100 people)
- Change in the way food or drink tastes
- Fast pulse
- Injection site reactions – such as bruising, pain, irritation, itching and rash
- Allergic reactions like rash, itching or hives
- A delay in the emptying of the stomach.

Not known (frequency cannot be estimated from the available data)
- Change in skin sensation.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

Yellow Card Scheme
Website: https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ozempic®

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pen label and carton after 'EXP'. The expiry date refers to the last day of that month.

Before opening:
Store in a refrigerator (2 °C – 8 °C). Do not freeze. Keep away from the cooling element. Keep the pen cap on in order to 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 it if it has been frozen.
- When you are not using the pen, keep the pen cap on in order to protect from light.

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

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. Contents of the pack and other information

What Ozempic® contains

- The active substance is semaglutide. One mL solution for injection contains 2.68 mg semaglutide. One pre-filled pen contains 8 mg semaglutide in 3 mL solution. Each dose contains 2 mg of semaglutide in 0.74 mL.
- The other ingredients are: disodium phosphate dihydrate, propylene glycol, phenol, water for injections, sodium hydroxide/hydrochloric acid (for pH adjustment). See also section 2, 'Sodium content'.

What Ozempic® looks like and contents of the pack
Ozempic® is a clear and colourless or almost colourless solution for injection in a pre-filled pen. Each pre-filled pen contains 3 mL solution, delivering 4 doses of 2 mg.

Ozempic® 2 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.

Marketing Authorisation Holder and Manufacturer
Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd
Denmark

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Ozempic® 2 mg
Solution for injection in pre-filled pen
semaglutide

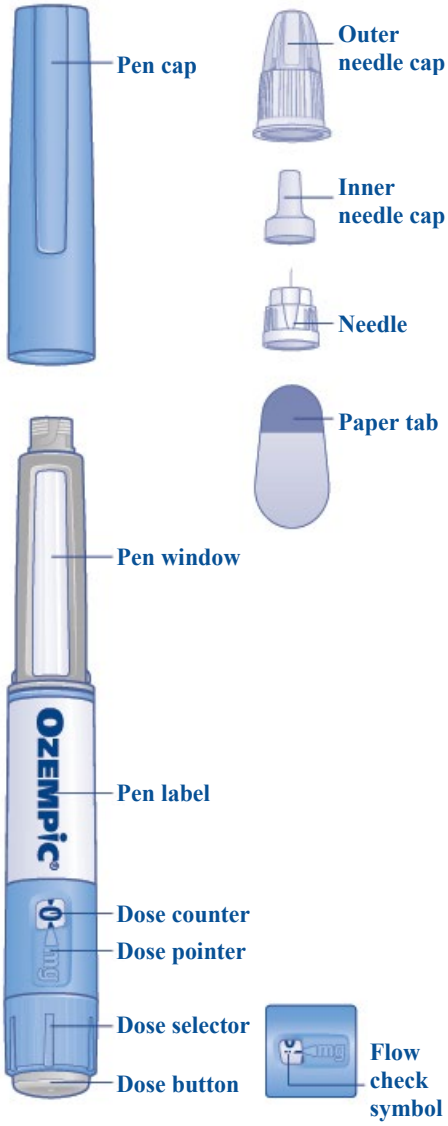
Instructions on how to use Ozempic® 2 mg solution for injection in pre-filled pen

Please read these instructions carefully before using your Ozempic® pre-filled pen.
Talk to your doctor, nurse or pharmacist about how to inject Ozempic® correctly.
Start by checking your pen to **make sure that it contains Ozempic® 2 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 knows how to use the Ozempic® pre-filled pen.
Your pen is a pre-filled dial-a-dose pen. It 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 inside the lid of the carton to keep track of how many injections you have taken and when you took the injections.

Your pen is designed to be used with 30G, 31G, and 32G disposable needles up to a length of 8 mm.
NovoFine® Plus needles are included in the pack.

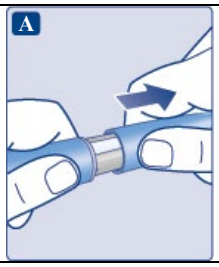
Ozempic® pre-filled pen and needle (example)

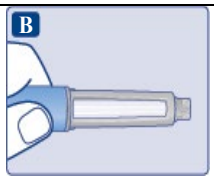
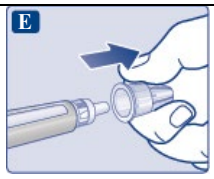
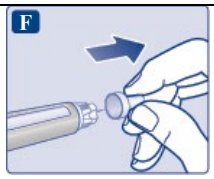
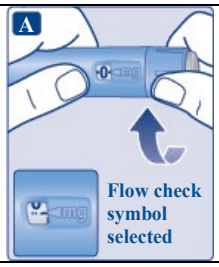


Important information
Pay special attention to these notes, as they are important for safe use of the pen.

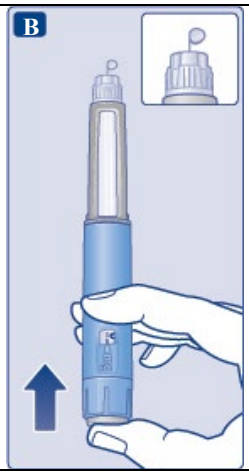
1. Prepare your pen with a new needle

- **Check the name and coloured label** of your pen, to make sure that it contains Ozempic® 2 mg. This is especially important if you take more than one type of injectable medicine. Using the wrong medicine could be harmful to your health.
- **Pull off the pen cap.**



• **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.	
• **Take a new needle.** Check the paper tab and the outer needle cap for damages that could affect sterility. If any damage is seen use a new needle. • **Tear off the paper tab.**	
Make sure to attach the needle correctly. • Push the needle **straight** onto the pen. • Turn until it is on **tight.**	
The needle is covered by two caps. You must remove both caps. If you forget to remove both caps, you will **not** inject any solution. • **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.	
• **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. See step 2 'Check the flow with each new pen'. **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 needle.**	
2. Check the flow with each new pen	
• If your pen is already in use, go to step 3 'Select your dose'. Only check the flow before your **first injection with each new pen**. • Turn the dose selector to **the flow check symbol** ( ) right past '0'. Make sure the flow check symbol lines up with the pointer.	

- 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.

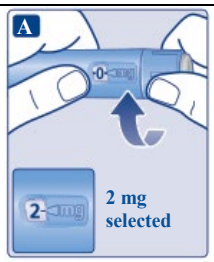


A small drop may remain at the needle tip, but it will not be injected.
If no drop appears, repeat step 2 ‘Check the flow with each new pen’ up to 6 times. If there is still no drop, change the needle and repeat step 2 ‘Check the flow with each new pen’ once more.
Dispose of the pen and use a new one if a drop of solution still does not appear.

⚠ **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

- **Turn the dose selector to select 2 mg.**
  Keep turning until the dose counter stops and shows 2 mg.



Only the dose counter and dose pointer will show that 2 mg has been selected.
You can only select 2 mg per dose. When your pen contains less than 2 mg, the dose counter stops before 2 is shown.
The dose selector clicks differently when turned forwards, backwards or past 2 mg. Do not count the pen clicks.

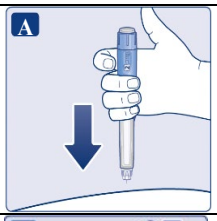
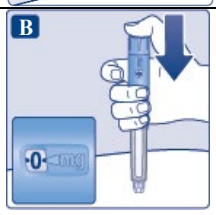
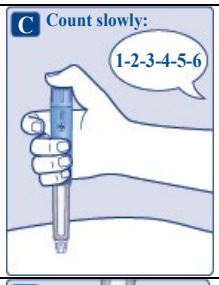
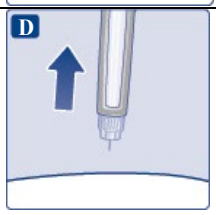
⚠ **Always use the dose counter and the dose pointer to see that 2 mg has been selected before injecting this medicine.**
Do not count the pen clicks.
Only doses of 2 mg must be selected with the dose selector. 2 mg must line up precisely with the dose pointer to ensure that you get a correct dose.

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 2, **at least 2 mg** is left in your pen.
  If the **dose counter stops before 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 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. Watch as the dose counter returns to '0'.** The '0' must line up with the dose pointer. You may then hear or feel a click. • **Continue pressing the dose button while keeping the needle in your skin.**	
• **Count slowly to 6, while keeping the dose button pressed.** • 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.** You can then release the dose button. If blood appears at the injection site, press lightly.	

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 returns to '0'.

How to identify a blocked or damaged needle

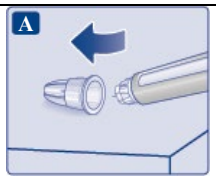
- If '0' does not appear in the dose counter after continuously pressing the dose button, you may have used a blocked or damaged needle.
- In this case, you have **not** received any medicine – even though the dose counter has moved from the original dose that you have set.

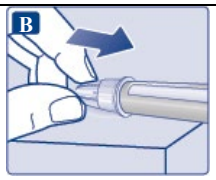
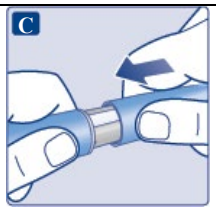
How to handle a blocked needle

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

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. • **Lead 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 as instructed by your doctor, nurse, pharmacist or local authorities.	
• **Put the pen cap on** your pen after each use to protect the solution from light.	

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 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. If this happens you might not get the intended effect of this medicine.

- **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, 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.** It may be cleaned 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.