

## APPROVED PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** **S4**

**OZEMPIC® 1,34 mg/ml solution for injection in pre-filled pen**

**Read all of this leaflet carefully before you start using**

**OZEMPIC®**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- OZEMPIC® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### **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.

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

- on its own if your blood sugar is not controlled well enough by diet and exercise alone, or
- with other medicines for diabetes – when they are not enough to control your blood sugar levels. These other medicines may include: oral antidiabetics (such as metformin, thiazolidinedione medicines (TZDs), sulfonylurea medicines, SGLT2 inhibitors) or insulin.

Ozempic® is used to reduce the risk of major cardiovascular events such as heart attack, stroke or death in adults with type 2 diabetes mellitus with known heart disease.

It is important that you keep following your diet and lifestyle advice received from your healthcare professional while using Ozempic®.

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

**Do not administer Ozempic®:**

- if you are allergic to semaglutide or any of the other ingredients of this medicine (listed under '**WHAT Ozempic® CONTAINS**').
- if you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC), or if you

have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

- if you are pregnant
- if you are breastfeeding your baby

Women who may become pregnant should use effective contraception while taking Ozempic.

### **Warnings and precautions**

Ozempic® is not an insulin and should not be used if:

- you have type 1 diabetes – your body does not produce any insulin
- you have diabetic ketoacidosis – a complication of diabetes that happens when the body is not able to break down glucose because there is not enough insulin.
- *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).

- *Dehydration*

During treatment with Ozempic®, you may experience feeling sick (nausea) or being sick (vomiting), and diarrhoea. These side effects can cause dehydration (loss of fluids). It is therefore important to drink plenty of fluids to prevent dehydration. Talk to your doctor if you have any questions or concerns.

- *Diabetic eye disease (retinopathy)*

Fast improvements in blood sugar control may lead to a temporary worsening of diabetic eye disease. This may require treatment or lead to a loss of vision. You should inform your doctor if you have diabetic eye disease (retinopathy) or if you experience eye problems during treatment with Ozempic®.

- Lumps in your neck may be due to a problem developing in your thyroid gland. Consult your doctor if you feel a lump developing.

- *Children and adolescents*

Ozempic® is not recommended in children and adolescents under 18 years as the safety and efficacy in this age group have not yet been established.

### **Using Ozempic® with food and drink:**

Ozempic® may be taken with or without meals.

### **Other medicines and OZEMPIC®**

*Always tell your healthcare professional if you are taking any other medicines. (This includes complementary or traditional medicines)*

Tell your healthcare professional if you are using medicines containing any of the following:

- sulfonylurea
- insulin

Combining these medicines with Ozempic® might increase the risk of getting low blood sugar (hypoglycaemia). Please see section

**‘POSSIBLE SIDE EFFECTS’** for the warning signs of low blood sugar. Your doctor may tell 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.

### **Pregnancy and breast-feeding**

Tell your doctor if you are pregnant, think you might be pregnant, or are planning to become pregnant. Ozempic® should not be used during pregnancy and for at least two months before a planned pregnancy because it is not known if it may affect your unborn child.

If you could become pregnant while using Ozempic®, you should use effective contraception.

Do not use this Ozempic® if you are breast-feeding. This is because Ozempic® may pass into breast milk.

### **Driving and using machines**

Low blood sugar (hypoglycaemia) may affect your ability to concentrate. Avoid driving or using machines if you get any signs of low blood sugar. See section **‘POSSIBLE SIDE EFFECTS’** for the warning signs of low blood sugar. Talk to your doctor for further information.

### **Important information about some of the ingredients of**

#### **OZEMPIC®**

##### *Sodium content*

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

### **OZEMPIC® contains**

The other ingredients are: disodium phosphate dihydrate, propylene glycol, phenol (as preservative), sodium hydroxide, hydrochloric acid and water for injections.

### **3. HOW TO USE OZEMPIC®**

Always use this Ozempic® exactly as your doctor has told you.

Check with your doctor, pharmacist or nurse if you are not sure.

#### **How much 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 once a week 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 do so.

#### **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, pharmacist or other healthcare professional will show you how to use it.

Detailed instructions for use are at the end of this leaflet.

### **When to administer Ozempic®**

- You should use Ozempic® once a week on the same day each week if possible.
- You can administer the injection yourself 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 2 days since your last injection of Ozempic®.

### **If you inject 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) or being sick (vomiting), or diarrhoea.

**If you forget to inject Ozempic®**

If you forgot to inject a dose and:

- it is 5 days or less since you should have administered Ozempic® injection, administer the injection 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 an extra dose or increase the dose to make up for a missed dose.

**Effects when treatment with Ozempic® is stopped:**

Do not stop using Ozempic® 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 other healthcare professional.

**4. POSSIBLE SIDE EFFECTS**

OZEMPIC® can have side effects.

Not all side effects reported for OZEMPIC® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using OZEMPIC®, please consult your doctor, pharmacist or other healthcare professional for advice.

### *Serious side effects*

#### Less frequent

- 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.
- 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.

### *Other side effects*

#### Frequent

- feeling sick (nausea)
- diarrhoea
- low blood sugar (hypoglycaemia) when OZEMPIC® is used with a 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.

- being sick (vomiting)
- 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
- feeling dizzy
- feeling tired
- weight loss
- less appetite
- gas (flatulence)
- increase of pancreatic enzymes (such as lipase and amylase)
- complications of diabetic eye disease (retinopathy).

#### Less frequent

- 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.

If you get any side effects, talk to your doctor, pharmacist or other healthcare professional. This includes any possible side effects not listed in this leaflet.

## Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse.

You can also report side effects to SAHPRA via the “**6.04**

**Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of OZEMPIC®.

## 5. How to store OZEMPIC®

- Keep Ozempic® out of reach of children.
- Do not use Ozempic® 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 (between 2 °C – 8 °C). Do not freeze. Keep away from the cooling element.

### During use

- You can keep the pen for 6 weeks when stored at a temperature at or below 30°C or in a refrigerator (between 2°C – 8°C) away from the cooling element. Do not freeze.
- When you are not using the pen, keep the pen cap on in order to protect from light.

Do not use this Ozempic® if the solution is not clear and colourless or almost colourless.

Discard any unused portion after 42 days (6 weeks).

## **6. Contents of the pack and other information**

### **What OZEMPIC® contains**

Ozempic® contains the active substance semaglutide. One ml solution for injection contains 1,34 mg semaglutide.

*Ozempic® 0,25 mg and 0,5 mg/dose pen:*

Each pre-filled pen contains 2 mg semaglutide in 1,5 ml solution

*Ozempic® 1 mg/dose pen:*

Each pre-filled pen contains 4 mg semaglutide in 3 ml solution

### **What OZEMPIC® looks like and contents of the pack**

Clear and colourless or almost colourless, free from visible particulate matter.

The primary packaging consists of a 1,5 ml or 3 ml glass (Type I glass) cartridge closed at the one end with a grey rubber plunger (chlorobutyl rubber) and at the other end with an aluminium cap with a cream laminate rubber disc (bromobutyl/polyisoprene) inserted.

There are two presentations of the pre-filled pen for Ozempic®:

- Ozempic® 0,25 mg and 0,5 mg/dose pen: Contains 1,5 ml solution for injection. The pen is designed to deliver doses of 0,25 mg or 0,5 mg.

This pen is intended to be used for dose escalation and maintenance treatment at the 0,5 mg dose.

The pen is light blue when capped, with PMS cool gray 6C dose button, on remove of the cap the pen consists of PMS cool gray 6C cartridge holder with light blue housing, labelled with summit red label.

- Ozempic® 1 mg/dose pen: Contains 3 ml solution for injection. The pen is designed to deliver doses of 1 mg only. This pen is to be used for maintenance treatment at the 1 mg dose only.

The pen is light blue when capped, with PMS cool gray 6C dose button, on remove of the cap the pen consists of PMS cool gray 6C cartridge holder with light blue housing, labelled with petrol blue label.

The pen(s) is/are packed in carton box

Pack sizes:

*Ozempic® 0,25 mg and 0,5 mg/dose pen:*

1 x 1,5 ml pre-filled pen including 6 disposable NovoFine® Plus needles

*Ozempic® 1 mg/dose pen:*

1 x 3 ml pre-filled pen including 4 disposable NovoFine® Plus needles

### **Holder of Certificate of Registration**

Novo Nordisk (Pty) Ltd

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10 Marion Street Office Park

Building C1, Sandton

Johannesburg, 2196

**This leaflet was last revised**

17 February 2023

**Registration number**

53/21.13/0497

## Instructions on how to use Ozempic® 0.25 mg, 0.5 mg/dose 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® 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.

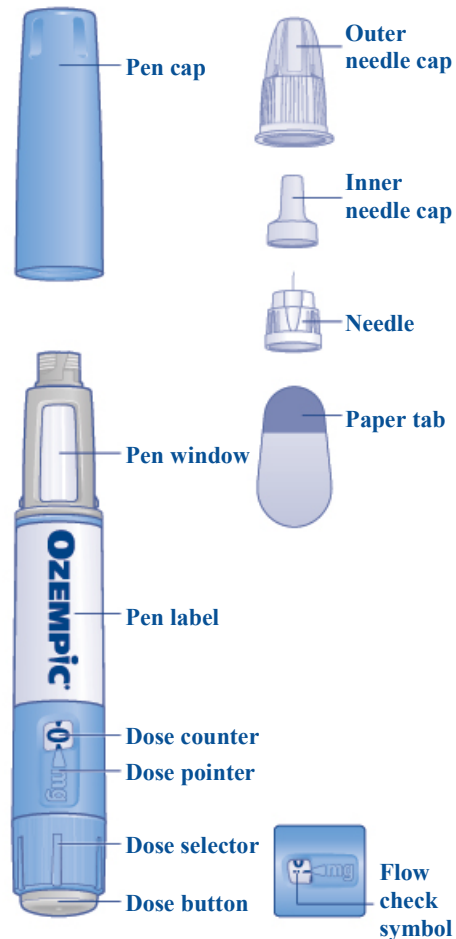
**If you are blind or have poor eyesight and cannot read the dose counter on the pen, do not use this pen without help.** Get help from a person with good eyesight who is trained to use the Ozempic® pre-filled pen.

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® and NovoTwist® disposable needles up to a length of 8 mm.

NovoFine® Plus needles are included in the pack.

Needles are medical devices.

### Ozempic® pre-filled pen and needle (example)

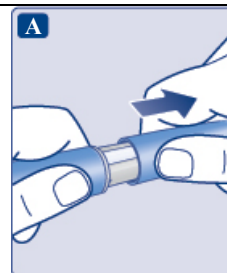


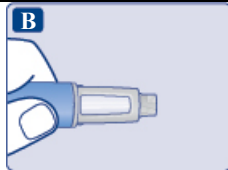
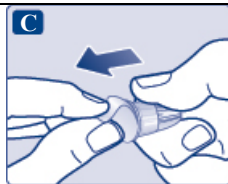
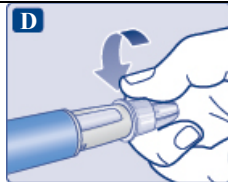
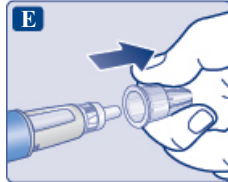
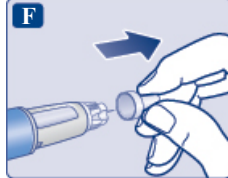
#### Important information

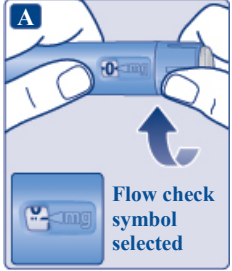
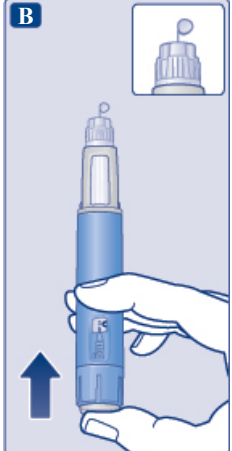
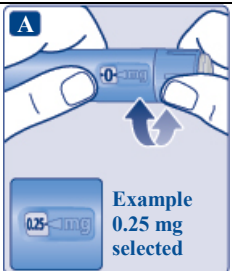
Pay special attention to these notes, as they are important for safe use of the pen.

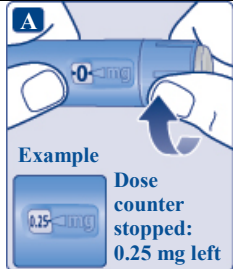
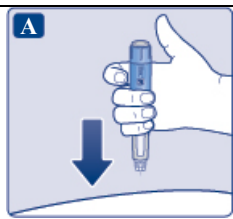
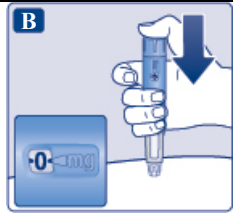
#### 1. Prepare your pen with a new needle

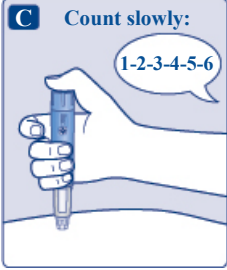
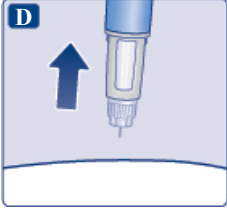
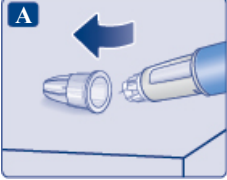
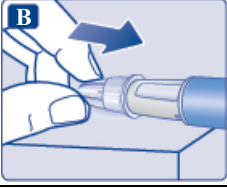
- **Check the name and coloured label** of your pen to make sure that it contains Ozempic® 0.25 mg, 0.5 mg/dose. This is especially important if you take more than one type of injectable medicine. Using the wrong medicine

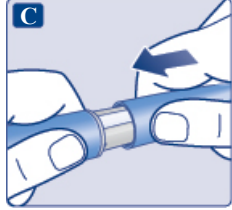


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| <p>could be harmful to your health.</p> <ul style="list-style-type: none"> <li>• <b>Pull off the pen cap.</b></li> </ul>                                                                                                                                                                                                                                                                                                                                                         |                                                                                      |
| <ul style="list-style-type: none"> <li>• <b>Check that the solution in your pen is clear</b> and colourless. Look through the pen window. If the solution looks cloudy or coloured, do not use the pen.</li> </ul>                                                                                                                                                                                                                                                               |    |
| <ul style="list-style-type: none"> <li>• <b>Take a new needle.</b> Check the paper tab and the outer needle cap for damages that could affect sterility. If any damage is seen use a new needle.</li> <li>• <b>Tear off the paper tab.</b></li> </ul>                                                                                                                                                                                                                            |    |
| <ul style="list-style-type: none"> <li>• <b>Push the needle straight onto the pen. Turn until it is on tight.</b></li> </ul>                                                                                                                                                                                                                                                                                                                                                     |   |
| <ul style="list-style-type: none"> <li>• <b>Pull off the outer needle cap and keep it for later.</b> You will need it after the injection, to safely remove the needle from the pen.</li> </ul>                                                                                                                                                                                                                                                                                  |  |
| <ul style="list-style-type: none"> <li>• <b>Pull off the inner needle cap and throw it away.</b> If you try to put it back on, you may accidentally stick yourself with the needle.</li> </ul> <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><b>Do not attach a new needle</b> to your pen until you are ready to take your injection.</p> |  |
| <p> <b>Always use a new needle for each injection.</b> This may prevent blocked needles, contamination, infection and inaccurate dosing.</p>                                                                                                                                                                                                                                                  |                                                                                      |
| <p> <b>Never use a bent or damaged needle.</b></p>                                                                                                                                                                                                                                                                                                                                            |                                                                                      |

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| <b>2. Check the flow</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                      |
| <ul style="list-style-type: none"> <li>• <b>Before your first injection with each new pen, check the flow.</b> If your pen is already in use, go to step 3 'Select your dose'.</li> <li>• Turn the dose selector <b>until the dose counter shows the flow check symbol</b> (  ).</li> </ul>                                                                                                                                                                                           |    |
| <ul style="list-style-type: none"> <li>• Hold the pen with the needle pointing up. <b>Press and hold in the dose button</b> 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.</li> </ul>                                                                                                                                                                                                                                                                                              |   |
| <p>A small drop may remain at the needle tip, but it will not be injected.<br/> <b>If no drop appears</b>, 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.<br/> <b>If a drop still does not appear</b>, dispose of the pen and use a new one.</p>                                                                                                                                                                                                                             |                                                                                      |
| <p> <b>Always make sure that a drop appears</b> at the needle tip before you use a new pen for the first time. This makes sure that the solution flows.<br/> If no drop appears, you will <b>not</b> inject any medicine even though the dose counter may move. <b>This may indicate a blocked or damaged needle.</b><br/> 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®.</p> |                                                                                      |
| <b>3. Select your dose</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                      |
| <ul style="list-style-type: none"> <li>• <b>Turn the dose selector until the dose counter shows your prescribed dose (0.25 mg or 0.5 mg).</b> If you select the wrong dose, you can turn the dose selector forwards or backwards to the correct dose.</li> </ul>                                                                                                                                                                                                                                                                                                       |  |

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| The pen can dial up to a maximum of 0.5 mg.                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                      |
| <p>The dose selector changes the dose. Only the dose counter and dose pointer will show how many mg you select per dose.</p> <p>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 is shown.</p> <p>The dose selector clicks differently when turned forwards, backwards or past the number of mg left. Do not count the pen clicks.</p>                                                 |                                                                                      |
| <p> <b>Always use the dose counter and the dose pointer to see how many mg you have selected before injecting this medicine.</b></p> <p>Do not count the pen clicks.</p> <p><b>Only doses of 0.25 mg or 0.5 mg must be selected with the dose selector.</b> The selected dose must line up precisely with the dose pointer to ensure that you get a correct dose.</p> |                                                                                      |
| <b>How much solution is left</b>                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                      |
| <ul style="list-style-type: none"> <li><b>To see how much solution is left</b>, use the dose counter: Turn the dose selector until the <b>dose counter stops</b>. If it shows 0.5, <b>at least 0.5 mg</b> is left in your pen. If the <b>dose counter stops before 0.5 mg</b>, there is not enough solution left for a full dose of 0.5 mg.</li> </ul>                                                                                                 |   |
| <p> If there is not enough solution left in your pen for a full dose, do not use it. Use a new Ozempic® pen.</p>                                                                                                                                                                                                                                                    |                                                                                      |
| <b>4. Inject your dose</b>                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                      |
| <ul style="list-style-type: none"> <li><b>Insert the needle into your skin</b> as your doctor or nurse has shown you.</li> <li><b>Make sure you can see the dose counter.</b> Do not cover it with your fingers. This could interrupt the injection.</li> </ul>                                                                                                                                                                                        |  |
| <ul style="list-style-type: none"> <li><b>Press and hold down the dose button until the dose counter shows 0.</b> The 0 must line up with the dose pointer. You may then hear or feel a click.</li> </ul>                                                                                                                                                                                                                                              |  |

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| <ul style="list-style-type: none"> <li>• <b>Keep the needle in your skin</b> after the dose counter has returned to 0 and <b>count slowly to 6.</b></li> <li>• 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.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |    |
| <ul style="list-style-type: none"> <li>• <b>Remove the needle from your skin.</b> If blood appears at the injection site, press lightly. Do not rub the area.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |    |
| <p>You may see a drop of solution at the needle tip after injecting. This is normal and does not affect your dose.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                      |
| <p> <b>Always watch the dose counter to know how many mg you inject.</b> Hold the dose button down until the dose counter shows 0.</p> <p><b>How to identify a blocked or damaged needle</b></p> <ul style="list-style-type: none"> <li>– If 0 does not appear in the dose counter after continuously pressing the dose button, you may have used a blocked or damaged needle.</li> <li>– In this case, you have <b>not</b> received any medicine – even though the dose counter has moved from the original dose that you have set.</li> </ul> <p><b>How to handle a blocked needle</b></p> <p>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.</p> <p><b>Never touch the dose counter when you inject.</b> This can interrupt the injection.</p> |                                                                                      |
| <p><b>5. After your injection</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                      |
| <ul style="list-style-type: none"> <li>• <b>Lead the needle tip into the outer needle cap</b> on a flat surface without touching the needle or the outer needle cap.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  |
| <ul style="list-style-type: none"> <li>• Once the needle is covered, <b>carefully push the outer needle cap completely on.</b></li> <li>• <b>Unscrew the needle</b> and dispose of it carefully.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  |

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| <ul style="list-style-type: none"> <li>• <b>Put the pen cap on your pen</b> after each use to protect the solution from light.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  |
| <p><b>Always dispose of the needle after each injection</b> to ensure convenient injections and prevent blocked needles. If the needle is blocked, you will <b>not</b> inject <b>any</b> medicine.</p> <p>When the pen is empty, throw it away <b>without</b> a needle on as instructed by your doctor, nurse, pharmacist or local authorities.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                    |
| <p> <b>Never try to put the inner needle cap back on the needle.</b> You may stick yourself with the needle.</p> <p> <b>Always remove the needle from your pen immediately after each injection.</b></p> <p>This may prevent blocked needles, contamination, infection, leakage of solution and inaccurate dosing.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                    |
| <p> <b>Further important information</b></p> <ul style="list-style-type: none"> <li>• Always keep your pen and needles <b>out of the sight and reach of others</b>, especially children.</li> <li>• <b>Never share</b> your pen or your needles with other people.</li> <li>• Caregivers must <b>be very careful when handling used needles</b> to prevent needle injury and cross-infection.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                    |
| <p><b>Caring for your pen</b></p> <p>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.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                    |
| <ul style="list-style-type: none"> <li>• <b>Do not leave the pen in a car</b> or another place where it can get too hot or too cold.</li> <li>• <b>Do not inject Ozempic® which has been frozen.</b> If you do that, you might not get the intended effect of this medicine.</li> <li>• <b>Do not inject Ozempic® which has been exposed to direct sunlight.</b> If you do that, you might not get the intended effect of this medicine.</li> <li>• <b>Do not expose your pen to dust, dirt or liquid.</b></li> <li>• <b>Do not wash, soak or lubricate your pen.</b> If necessary, clean it with a mild detergent on a moistened cloth.</li> <li>• <b>Do not drop your pen</b> 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.</li> <li>• <b>Do not try to refill your pen.</b> Once empty, it must be disposed of.</li> <li>• <b>Do not try to repair your pen</b> or pull it apart.</li> </ul> |                                                                                    |

## Instructions on how to use Ozempic® 1 mg/dose 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/dose**, then look at the illustrations below to get to know the different parts of your pen and needle.

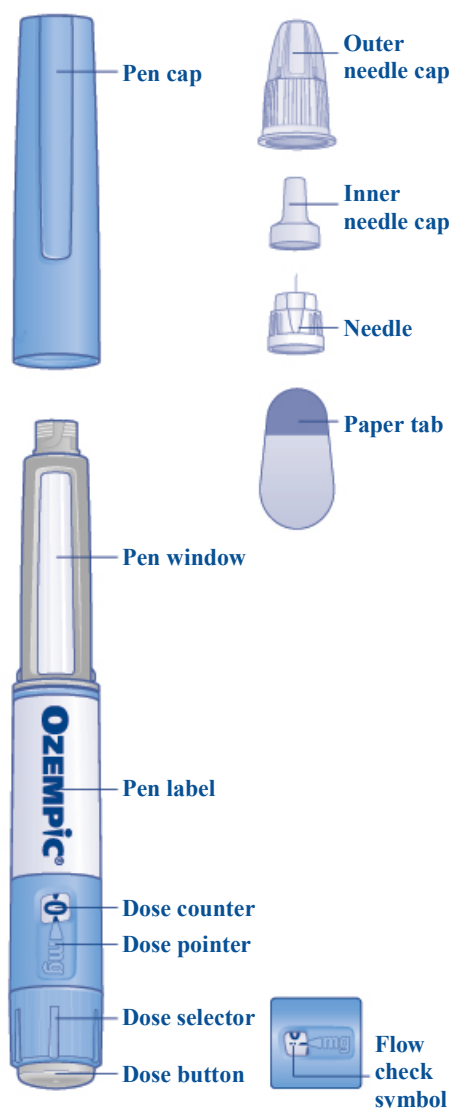
**If you are blind or have poor eyesight and cannot read the dose counter on the pen, do not use this pen without help.** Get help from a person with good eyesight who is trained to use the Ozempic® pre-filled pen.

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.

Needles are medical devices.

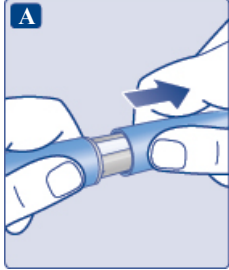
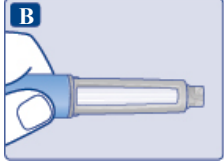
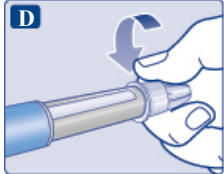
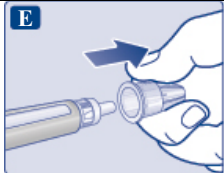
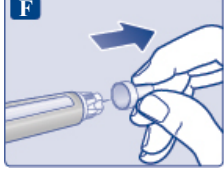
### Ozempic® pre-filled pen and needle (example)

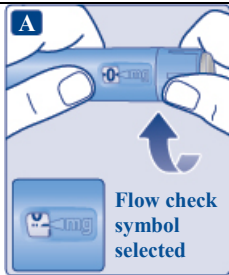
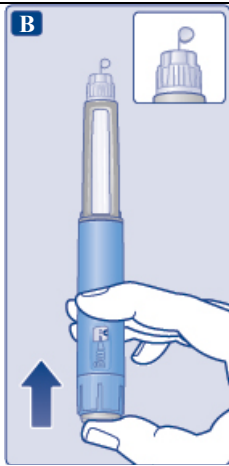


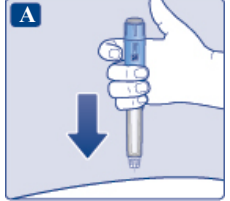
### Important information

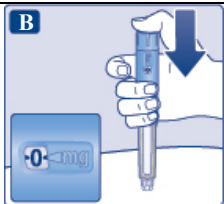
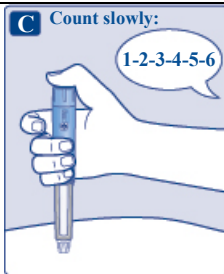
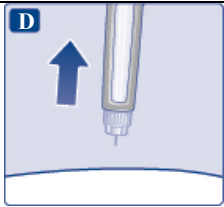
Pay special attention to these notes, as they are important for safe use of the pen.

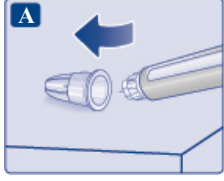
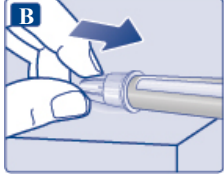
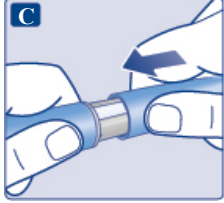
### 1. Prepare your pen with a new needle

|                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                      |
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| <ul style="list-style-type: none"> <li>• <b>Check the name and coloured label</b> of your pen to make sure that it contains Ozempic® 1 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.</li> <li>• <b>Pull off the pen cap.</b></li> </ul>                                |    |
| <ul style="list-style-type: none"> <li>• <b>Check that the solution in your pen is clear</b> and colourless. Look through the pen window. If the solution looks cloudy or coloured, do not use the pen.</li> </ul>                                                                                                                                                              |    |
| <ul style="list-style-type: none"> <li>• <b>Take a new needle.</b> Check the paper tab and the outer needle cap for damages that could affect sterility. If any damage is seen use a new needle.</li> <li>• <b>Tear off the paper tab.</b></li> </ul>                                                                                                                           |    |
| <ul style="list-style-type: none"> <li>• <b>Push the needle straight onto the pen.</b> Turn until it is on tight.</li> </ul>                                                                                                                                                                                                                                                    |  |
| <ul style="list-style-type: none"> <li>• <b>Pull off the outer needle cap and keep it for later.</b> You will need it after the injection, to safely remove the needle from the pen.</li> </ul>                                                                                                                                                                                 |  |
| <ul style="list-style-type: none"> <li>• <b>Pull off the inner needle cap and throw it away.</b> If you try to put it back on, you may accidentally stick yourself with the needle.</li> </ul> <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> |  |

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| <p><b>Do not attach a new needle</b> to your pen until you are ready to take your injection.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                     |
| <p> <b>Always use a new needle for each injection.</b><br/>This may prevent blocked needles, contamination, infection and inaccurate dosing.</p>                                                                                                                                                                                                                                                                                                                                           |                                                                                     |
| <p> <b>Never use a bent or damaged needle.</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                     |
| <p><b>2. Check the flow</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                     |
| <ul style="list-style-type: none"> <li>• <b>Before your first injection with each new pen, check the flow.</b> If your pen is already in use, go to step 3 'Select your dose'.</li> <li>• Turn the dose <b>selector</b> until <b>the dose counter shows the flow check symbol (  ).</b></li> </ul>                                                                                                                                                         |   |
| <ul style="list-style-type: none"> <li>• Hold the pen with the needle pointing up. <b>Press and hold in the dose button</b> 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.</li> </ul>                                                                                                                                                                                                                                                                                                   |  |
| <p>A small drop may remain at the needle tip, but it will not be injected.</p> <p><b>If no drop appears</b>, 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.</p> <p><b>If a drop still does not appear</b>, dispose of the pen and use a new one.</p>                                                                                                                                                                                                                              |                                                                                     |
| <p> <b>Always make sure that a drop appears</b> at the needle tip before you use a new pen for the first time. This makes sure that the solution flows.</p> <p>If no drop appears, you will <b>not</b> inject any medicine, even though the dose counter may move. <b>This may indicate a blocked or damaged needle.</b></p> <p>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®.</p> |                                                                                     |
| <p><b>3. Select your dose</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                     |

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| <ul style="list-style-type: none"> <li>• <b>Turn the dose selector to select 1 mg.</b><br/>Keep turning until the dose counter stops and shows 1 mg.</li> </ul>                                                                                                                                                                                                                                                      |    |
| <p>Only the dose counter and dose pointer will show that 1 mg has been selected.</p> <p>You can only select 1 mg per dose. When your pen contains less than 1 mg, the dose counter stops before 1 is shown.</p> <p>The dose selector clicks differently when turned forwards, backwards or past 1 mg. Do not count the pen clicks.</p>                                                                               |                                                                                      |
| <p> <b>Always use the dose counter and the dose pointer to see that 1 mg has been selected before injecting this medicine.</b><br/>Do not count the pen clicks.<br/><b>Only doses of 1 mg must be selected with the dose selector.</b> 1 mg must line up precisely with the dose pointer to ensure that you get a correct dose.</p> |                                                                                      |
| <p><b>How much solution is left</b></p>                                                                                                                                                                                                                                                                                                                                                                              |                                                                                      |
| <ul style="list-style-type: none"> <li>• <b>To see how much solution is left, use the dose counter:</b><br/>Turn the dose selector until the <b>dose counter stops</b>.<br/>If it shows 1, <b>at least 1 mg</b> is left in your pen.<br/>If the <b>dose counter stops before 1 mg</b>, there is not enough solution left for a full dose of 1 mg.</li> </ul>                                                         |  |
| <p> If there is not enough solution left in your pen for a full dose, do not use it. Use a new Ozempic® pen.</p>                                                                                                                                                                                                                  |                                                                                      |
| <p><b>4. Inject your dose</b></p>                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                      |
| <ul style="list-style-type: none"> <li>• <b>Insert the needle into your skin</b> as your doctor or nurse has shown you.</li> <li>• <b>Make sure you can see the dose counter.</b> Do not cover it with your fingers. This could interrupt the injection.</li> </ul>                                                                                                                                                  |  |

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| <ul style="list-style-type: none"> <li>• <b>Press and hold down the dose button until the dose counter shows 0.</b> The 0 must line up with the dose pointer. You may then hear or feel a click.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |  |
| <ul style="list-style-type: none"> <li>• <b>Keep the needle in your skin</b> after the dose counter has returned to 0 and <b>count slowly to 6.</b></li> <li>• 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.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |  |
| <ul style="list-style-type: none"> <li>• <b>Remove the needle from your skin.</b> If blood appears at the injection site, press lightly. Do not rub the area.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |  |
| <p>You may see a drop of solution at the needle tip after injecting. This is normal and does not affect your dose.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                    |
| <p> <b>Always watch the dose counter to know how many mg you inject.</b> Hold the dose button down until the dose counter shows 0.</p> <p><b>How to identify a blocked or damaged needle</b></p> <ul style="list-style-type: none"> <li>- If 0 does not appear in the dose counter after continuously pressing the dose button, you may have used a blocked or damaged needle.</li> <li>- In this case, you have <b>not</b> received any medicine – even though the dose counter has moved from the original dose that you have set.</li> </ul> <p><b>How to handle a blocked needle</b></p> <p>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.</p> <p><b>Never touch the dose counter when you inject.</b> This can interrupt the injection.</p> |                                                                                    |
| <p><b>5. After your injection</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                    |

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| <ul style="list-style-type: none"> <li>• <b>Lead the needle tip into the outer needle cap</b> on a flat surface without touching the needle or the outer needle cap.</li> </ul>                                                                                                                                                                                                                                                                                                              |  |
| <ul style="list-style-type: none"> <li>• Once the needle is covered, <b>carefully push the outer needle cap completely on.</b></li> <li>• <b>Unscrew the needle</b> and dispose of it carefully.</li> </ul>                                                                                                                                                                                                                                                                                  |  |
| <ul style="list-style-type: none"> <li>• <b>Put the pen cap on</b> your pen after each use to protect the solution from light.</li> </ul>                                                                                                                                                                                                                                                                                                                                                    |  |
| <p><b>Always dispose of the needle after each injection</b> to ensure convenient injections and prevent blocked needles. If the needle is blocked, you will <b>not</b> inject <b>any</b> medicine.</p> <p>When the pen is empty, throw it away <b>without</b> a needle on as instructed by your doctor, nurse, pharmacist or local authorities.</p>                                                                                                                                          |                                                                                    |
| <p> <b>Never try to put the inner needle cap back on the needle.</b> You may stick yourself with the needle.</p> <p> <b>Always remove the needle from your pen immediately after each injection.</b></p> <p>This may prevent blocked needles, contamination, infection, leakage of solution and inaccurate dosing.</p> |                                                                                    |
| <p> <b>Further important information</b></p>                                                                                                                                                                                                                                                                                                                                                              |                                                                                    |
| <ul style="list-style-type: none"> <li>• Always keep your pen and needles <b>out of the sight and reach of others</b>, especially children.</li> <li>• <b>Never share</b> your pen or your needles with other people.</li> <li>• Caregivers must <b>be very careful when handling used needles</b> to prevent needle injury and cross-infection.</li> </ul>                                                                                                                                  |                                                                                    |
| <p><b>Caring for your pen</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                    |
| <p>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.</p>                                                                                                                                                                                                                                                                                                                               |                                                                                    |
| <ul style="list-style-type: none"> <li>• <b>Do not leave the pen in a car</b> or another place where it can get too hot or too cold.</li> <li>• <b>Do not inject Ozempic® which has been frozen.</b> If you do that, you might not get the intended effect of this medicine.</li> </ul>                                                                                                                                                                                                      |                                                                                    |

- **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 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.