

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

**Ozempic®**

(semaglutide injection)

Read this carefully before you start taking **Ozempic®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Ozempic®**.

#### **Serious Warnings and Precautions** **Possible Risk of thyroid tumours, including cancer**

As part of drug testing, semaglutide, the active ingredient in Ozempic® was given to rats and mice in long term studies. In these studies, semaglutide caused both rats and mice to develop medullary thyroid tumours, some of which were cancer. It is not known if semaglutide will cause thyroid tumours or a rare type of thyroid cancer called medullary thyroid cancer in people. Do not use Ozempic® 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).

While taking Ozempic®, tell your doctor if you get a lump or swelling in your neck, hoarseness, trouble swallowing or shortness of breath. These may be symptoms of thyroid cancer. You should discuss any safety concerns you have about the use of Ozempic® with your doctor.

#### **What is Ozempic® used for?**

- Ozempic® contains the active substance semaglutide. It is used to lower blood sugar (glucose) in adults with type 2 diabetes.
- Ozempic® is used on its own if your blood sugar level is not properly controlled by diet and exercise alone and you cannot use metformin.
- Ozempic® is used in combination with one or more 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, sulfonylurea, or sodium glucose co-transporter 2 inhibitor medicines) or insulin.
- It is important that you keep following any diet and lifestyle advice from your doctor, pharmacist or nurse while using Ozempic®.
- Ozempic® is not a substitute for insulin. Ozempic® should not be used in patients with Type 1 diabetes mellitus (formerly known as insulin-dependent diabetes mellitus or IDDM), or for treatment of diabetic ketoacidosis.

#### **How does Ozempic® work?**

Ozempic® belongs to a class of medicines called GLP-1 receptor agonists (glucagon-like peptide-1 receptor agonists). Ozempic® helps your body make more insulin when your blood sugar is high.

**What are the ingredients in Ozempic®?**

Medicinal ingredients: semaglutide. One mL solution for injection contains 0.68 mg, 1.34 mg or 2.68 mg semaglutide.

Non-medicinal ingredients: disodium phosphate dihydrate, propylene glycol, phenol, and water for injections.

**Ozempic® comes in the following dosage forms:**

Ozempic® is supplied as a clear and colourless solution for injection in a pre-filled pen.

Ozempic® is available in a carton of 1 disposable, pre-filled, multi-dose pen delivering doses of 0.25 mg or 0.5 mg, including 6 disposable needles. This pack size is intended to be used for dose escalation and maintenance treatment at the 0.5 mg dose. The pen contains 1.5 mL or 3 mL solution.

Ozempic® is available in a carton of 1 disposable, pre-filled, multi-dose pen delivering only doses of 1 mg, including 4 disposable needles. This pack size is intended to be used for maintenance treatment at the 1 mg dose only. The pen contains 3 mL solution.

Ozempic® is also available in a carton of 1 disposable, pre-filled, multi-dose pen delivering only doses of 2 mg, including 4 disposable needles. This pack size is intended to be used for maintenance treatment at the 2 mg dose only. The pen contains 3 mL solution.

**Do not use Ozempic® if:**

- You are allergic to semaglutide or any of the other ingredients of this medicine.
- You or a member of your family has ever had medullary thyroid cancer (MTC).
- You have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- You are pregnant or breastfeeding.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Ozempic®. Talk about any health conditions or problems you may have, including if you:**

- or a member of your family has or has had medullary thyroid carcinoma (MTC), or if you have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- Have type 1 diabetes.
- Have ever had diabetic ketoacidosis (increased ketones in the blood or urine).
- Have ever had an allergic reaction to Ozempic®.
- Have a high heart rate (fast pulse).
- Have ever had pancreatitis.
- Are breastfeeding or plan to breastfeed.
- Are pregnant or plan to become pregnant.
- Have end stage renal disease.
- Have gastrointestinal (digestive) problems, including severe vomiting, diarrhea and/or dehydration.
- Have hepatic (liver) disease.
- Have diabetic retinopathy.

**Other warnings you should know about:****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.

#### Pregnancy and breastfeeding

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®, it is recommended to use contraception.

Do not use this medicine if you are breast-feeding. This is because it is not known if Ozempic® passes into breast milk.

#### Driving and using machines

Low blood sugar (hypoglycemia) may affect your ability to concentrate. Avoid driving or using machines if you get any signs of low blood sugar. See *What are possible side effects from using Ozempic®* for the warning signs of low blood sugar. You may feel dizzy when taking Ozempic®, especially if your dose is being increased. If you feel dizzy, avoid driving or using machines. Talk to your doctor for further information.

#### 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).

#### Effects on the digestive system, including dehydration

During treatment with Ozempic®, you may experience feeling sick (nausea) or being sick (vomiting), and diarrhea. 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®.

#### Low blood sugar (hypoglycemia)

Taking a sulfonylurea medicine or insulin with Ozempic® might increase the risk of getting low blood sugar levels (hypoglycemia). 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.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

In particular, tell your doctor, pharmacist or nurse 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 (hypoglycemia). Please see *What are possible side effects from using Ozempic®* for the warning

signs of low blood sugar. Your doctor may tell you to lower your regular dose levels of these drugs when adding Ozempic® treatment.

**The following may interact with Ozempic®:**

The following list includes some, but not all, of the drugs that may increase your heart rate. You should check with your doctor or pharmacist before taking any other medication with Ozempic®:

- Drugs to treat hypertension.
- Drugs to treat heart failure.
- Drugs to treat HIV infection.
- Drugs to treat attention deficit-hyperactivity disorder.
- Drugs to suppress appetite/cause weight loss.
- Decongestants.
- Drugs to treat asthma.

**How to take Ozempic®:**

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 Diabetes Nurse Educator will show you how to use it.

Detailed instructions for use are on the other side of this leaflet.

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

You should use Ozempic® once a week on the same day each week if possible. You can give yourself the injection at any time of the day – regardless of meals. To help you remember to inject Ozempic® once a week only, it is recommended to note the chosen weekday (e.g. Wednesday) on the carton. You can also write the date on the carton every time you have injected Ozempic®.

If necessary you can change the day of your weekly injection of Ozempic® as long as it has been at least 2 days since your last injection of Ozempic®.

Do not stop using Ozempic® without talking to your doctor. If you stop using it, your blood sugar levels may increase.

**Usual dose:**

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.

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.

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

**Overdose:**

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 diarrhea.

If you think you have taken too much Ozempic®, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

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

**What are possible side effects from using Ozempic®?**

These are not all the possible side effects you may feel when taking Ozempic®. If you experience any side effects not listed here, contact your healthcare professional.

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common: may affect more than 1 in 10 people

- Feeling sick (nausea) – this usually goes away over time
- Diarrhea – this usually goes away over time
- Low blood sugar (hypoglycemia) 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.

Common: may affect up to 1 in 10 people

- Being sick (vomiting)
- Low blood sugar (hypoglycemia) when Ozempic® is used with an oral antidiabetic other than a sulfonylurea
- Indigestion
- Inflamed stomach ('gastritis') - the signs also 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)

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 emptying of the stomach

Unknown:

- Ileus (Bowel obstruction, a severe form of constipation with additional symptoms such as stomach ache, bloating, vomiting etc.)

Rare: may affect up to 1 in 1,000 people

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.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>COMMON</b> Diabetic retinopathy complications – complications of diabetic eye disease/diabetic eye problems		√	
<b>UNCOMMON</b> Pancreatitis (severe and ongoing pain in the stomach area which could be a sign of inflamed pancreas)		√	√
Severe hypoglycemia* (low blood sugar) symptoms: feeling confused, fits and passing out		√	√
<b>RARE</b> Severe allergic reaction (anaphylactic reaction, angioedema) symptoms: breathing problems, swelling of face, lips, tongue and/or throat		√	√

with difficulty swallowing and a fast heartbeat			
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\*The risk of severe hypoglycemia may be higher when you also take other diabetes medications.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

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.

During use:

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

Do not use this medicine if the solution is not clear and 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.

### If you want more information about Ozempic®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website ([www.novonordisk.ca](http://www.novonordisk.ca)), or by calling 1-800-465-4334.

This leaflet was prepared by Novo Nordisk Canada Inc.

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**Instructions on how to use Ozempic® solution for injection in pre-filled pen  
0.25 mg or 0.5 mg doses**

**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® 0.25 mg or 0.5 mg doses**, 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.

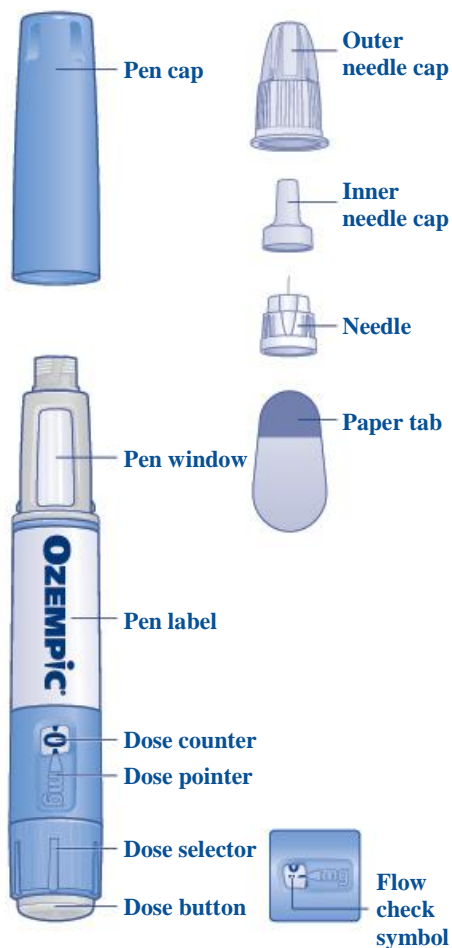
One unused pen contains:

- 4 doses of 0.25 mg (starting dose) *and* 2 doses of 0.5 mg
- **or** 4 doses of 0.5 mg.

Your pen is designed to be used with NovoFine® disposable needles up to a length of 8 mm.

Disposable needles are included in the pack.

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

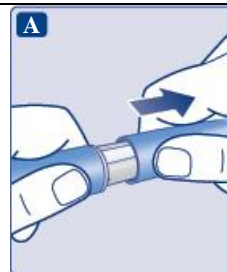










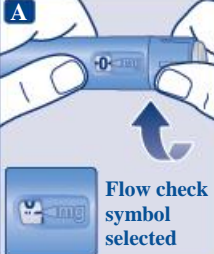
**⚠ Important information**


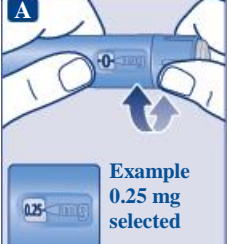
Pay special attention to these notes, as they are important for safe use of the pen.

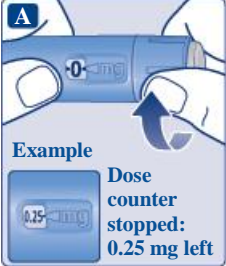



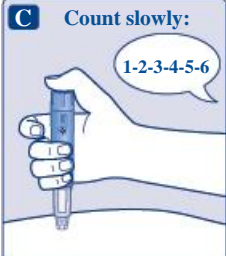


**1. Prepare your pen with a new needle**

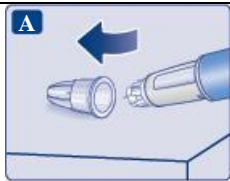
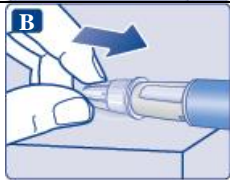
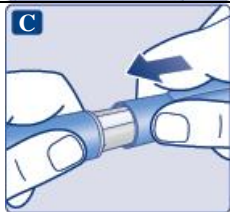



- **Check the name and coloured label** of your pen to make sure that it contains Ozempic® 0.25 or 0.5 mg doses. This is especially important if you take more than one type of injectable medicine. Using the wrong medicine could be harmful to your health.
- **Pull off the pen cap.**



<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> and tear off the paper tab. If the paper tab is broken, do not use the needle, as sterility is not guaranteed.</li> </ul>		
<p><b>Make sure to attach the needle correctly.</b></p> <ul style="list-style-type: none"> <li>• Push the needle <b>straight</b> onto the pen.</li> <li>• Turn until it is on <b>tight</b>.</li> </ul>		
<p><b>The needle is covered by two caps. You must remove both caps.</b> If you forget to remove both caps, you will <b>not</b> inject any solution.</p> <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. <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>		
<p><b>2. Check the flow with each new pen</b></p> <ul style="list-style-type: none"> <li>• If your pen is already in use, go to step 3 'Select your dose'. Only check the flow before your <b>first injection with each new pen</b>.</li> <li>• Turn the dose selector <b>to the flow check symbol</b> (  ) right past '0'. Make sure the flow check symbol lines up with the pointer.</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.  <b>If no drop appears</b>, 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.</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.  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>  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 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.  The pen can dial up to a maximum of 0.5 mg.</li> </ul>	
<p>The dose selector changes the dose. Only the dose counter and dose pointer will show how many mg you select per dose.  You can select up to 0.5 mg per dose. When your pen contains less than 0.5 mg, the dose counter stops before 0.5 is shown.  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>  <b>Do not count the pen clicks.</b>  <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><b>A</b></p> <p>Example Dose counter stopped: 0.25 mg left</p>
<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>	 <p><b>B</b></p>
<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>	 <p><b>C</b></p>
<ul style="list-style-type: none"> <li>• Continue pressing the dose button while keeping the needle in your skin. <b>Count slowly to 6 while keeping the dose button pressed.</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>	 <p><b>D</b></p>
<ul style="list-style-type: none"> <li>• <b>Remove the needle from your skin. You can then release the dose button.</b> If blood appears at the injection site, press lightly.</li> </ul>	 <p><b>E</b></p>
<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</p>	

step 1 'Prepare your pen with a new needle'. Make sure you select the full dose you need.	
<b>Never touch the dose counter when you inject.</b> This can interrupt the injection.	
<b>5. After your injection</b>	
<b>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.</b> Unscrew the needle and dispose of it carefully <b>as instructed by your doctor, nurse, pharmacist or local authorities.</b>	
<ul style="list-style-type: none"> <li>Lead the needle tip into the outer needle cap 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>	
<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. When the pen is empty, throw it away <b>without</b> a needle on as instructed by your doctor, nurse, pharmacist or local authorities.	
 <b>Never try to put the inner needle cap back on the needle.</b> You may stick yourself with the needle.	
 <b>Always remove the needle from your pen immediately after each injection.</b> This may prevent blocked needles, contamination, infection, leakage of solution and inaccurate dosing.	
 <b>Further important information</b>	
<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> <li>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.</li> </ul>	
<b>Caring for your pen</b>	
Treat your pen with care. Rough handling or misuse may cause inaccurate dosing, which may lead to high blood sugar levels or abdominal discomfort such as nausea or vomiting.	
<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, your blood sugar level may get too high or you might feel abdominal discomfort such as nausea or vomiting.</li> <li><b>Do not inject Ozempic® which has been exposed to direct sunlight.</b> If you do that, your blood sugar level may get too high.</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> It may be cleaned 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</li> </ul>	

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.

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

**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.

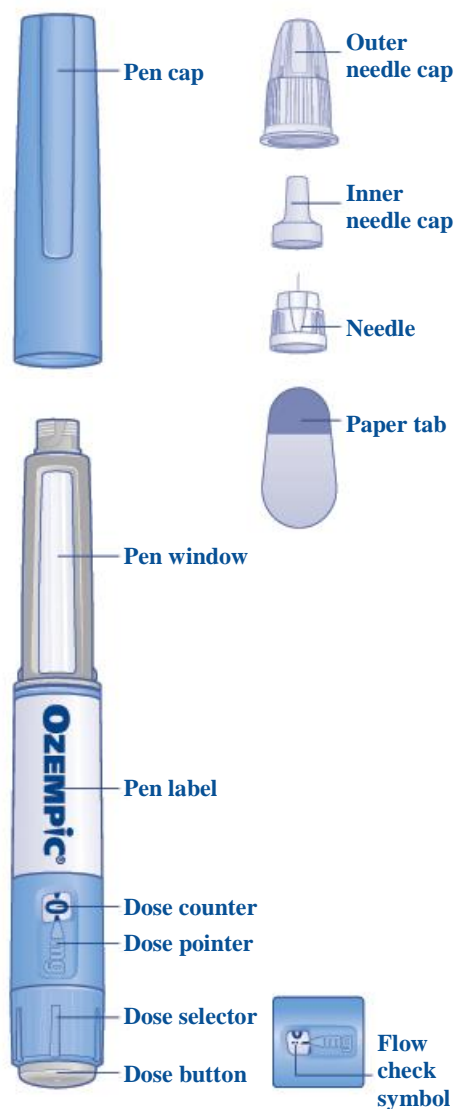
Start by checking your pen to **make sure that it contains Ozempic® 1 mg**, then look at the illustrations below to get to know the different parts of your pen and needle.

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

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

Disposable needles are included in the pack.

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




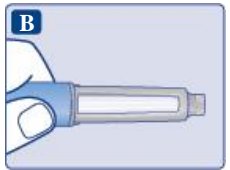


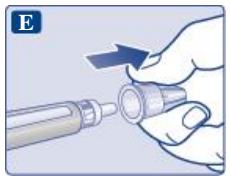
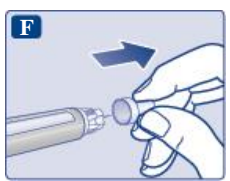



### Important information

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

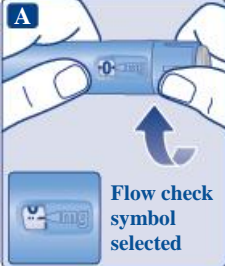


#### 1. Prepare your pen with a new needle



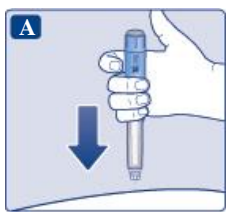
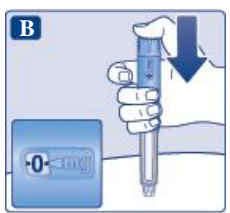
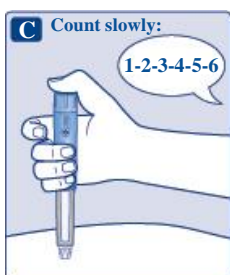
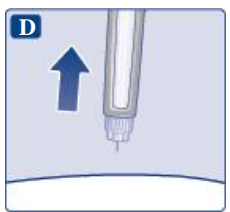

- **Check the name and coloured label** of your pen, to make sure that it contains Ozempic® 1 mg. This is especially important if you take more than one type of injectable medicine. Using the wrong medicine could be harmful to your health.
- **Pull off the pen cap.**

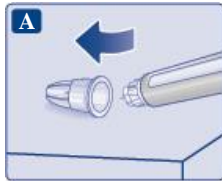




		
<ul style="list-style-type: none"> <li>• <b>Check that the solution in your pen is clear</b> and colourless. Look through the pen window. If the solution looks cloudy or coloured, do not use the pen.</li> </ul>		
<ul style="list-style-type: none"> <li>• <b>Take a new needle</b> and tear off the paper tab. If the paper tab is broken, do not use the needle, as sterility is not guaranteed.</li> </ul>		
<p><b>Make sure to attach the needle correctly.</b></p> <ul style="list-style-type: none"> <li>• Push the needle <b>straight</b> onto the pen.</li> <li>• Turn until it is on <b>tight</b>.</li> </ul>		
<p><b>The needle is covered by two caps. You must remove both caps.</b> If you forget to remove both caps, you will <b>not</b> inject any solution.</p> <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. <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>		
<p><b>2. Check the flow with each new pen</b></p>		
<ul style="list-style-type: none"> <li>• If your pen is already in use, go to step 3 'Select your dose'. Only check the flow before your <b>first injection with each new pen</b>.</li> <li>• Turn the dose selector <b>to the flow check symbol</b> (  ) right past '0'. Make sure the flow check symbol lines up with the pointer.</li> </ul>		



	 <p>Flow check symbol selected</p>
<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. <b>If no drop appears</b>, 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' once more with each new pen. Dispose of the pen and use a new one if a drop still does not appear.</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. 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> 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>	
<ul style="list-style-type: none"> <li><b>Turn the dose selector to select 1 mg.</b> Keep turning until the dose counter stops and shows 1 mg.</li> </ul>	 <p>1 mg selected</p>
<p>Only the dose counter and dose pointer will show that 1 mg has been selected. You can only select 1 mg per dose. When your pen contains less than 1 mg, the dose counter stops before 1 is shown. 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</b> before injecting this medicine. <b>Do not count the pen clicks.</b> <b>Only doses of 1 mg must be selected with the dose selector.</b> 1 mg must line up precisely with</p>	

the dose pointer to ensure that you get a correct dose.	
<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 1, <b>at least 1 mg</b> is left in your pen. 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>	
 If there is not enough solution left in your pen for a full dose, do not use it. Use a new Ozempic® pen.	
<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>Watch as the dose counter returns to 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>Continue pressing the dose button while keeping the needle in your skin. 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. You can then release the dose button.</b> If blood appears at the injection site, press lightly. Hold the dose button down until the dose counter returns to '0'.</li> </ul>	
You may see a drop of solution at the needle tip after injecting. This is normal and does not affect your dose.	
 <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.	
<b>How to identify a blocked or damaged needle</b>	

<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>	
<b>5. After your injection</b>	
<p><b>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.</b></p> <p>Unscrew the needle and dispose of it carefully <b>as instructed by your doctor, nurse, pharmacist or local authorities.</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>	
<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>	
<b>⚠ Further important information</b>	
<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> <li>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.</li> </ul>	
<b>Caring for your pen</b>	
Treat your pen with care. Rough handling or misuse may cause inaccurate dosing, which may lead to	

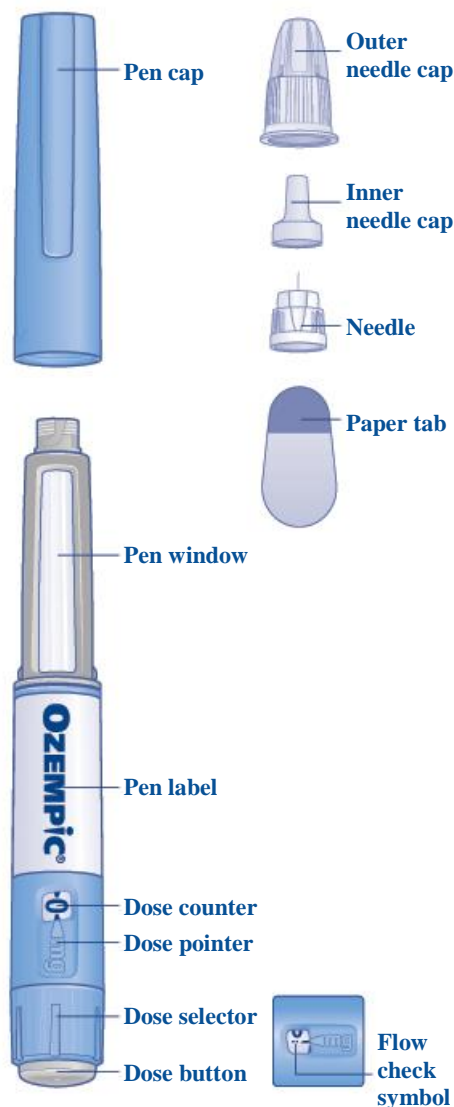
high blood sugar levels or abdominal discomfort such as nausea or vomiting.

- **Do not leave the pen in a car** or another place where it can get too hot or too cold.
- **Do not inject Ozempic® which has been frozen.** If you do that, your blood sugar level may get too high or you might feel abdominal discomfort such as nausea or vomiting.
- **Do not inject Ozempic® which has been exposed to direct sunlight.** If you do that, your blood sugar level may get too high.
- **Do not expose your pen to dust, dirt or liquid.**
- **Do not wash, soak or lubricate your pen.** 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.

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

**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 is trained 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. Your pen is designed to be used with NovoFine® disposable needles up to a length of 8 mm. Disposable needles are included in the pack.

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


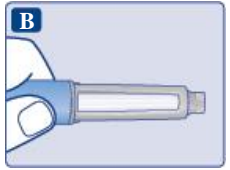


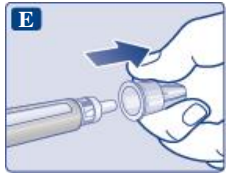
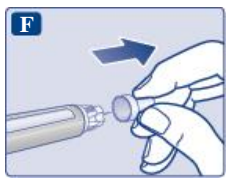





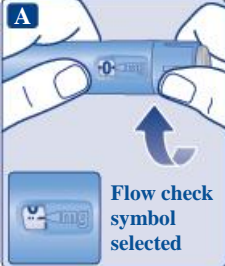


**Important information**

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



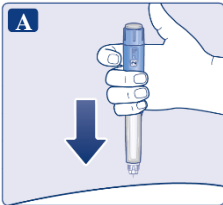


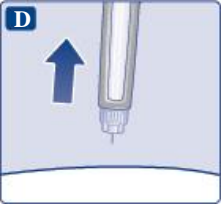

**1. Prepare your pen with a new needle**

- **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.**

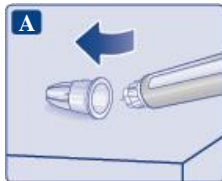





		
<ul style="list-style-type: none"> <li>• <b>Check that the solution in your pen is clear</b> and colourless. Look through the pen window. If the solution looks cloudy or coloured, do not use the pen.</li> </ul>		
<ul style="list-style-type: none"> <li>• <b>Take a new needle</b> and tear off the paper tab. If the paper tab is broken, do not use the needle, as sterility is not guaranteed.</li> </ul>		
<p><b>Make sure to attach the needle correctly.</b></p> <ul style="list-style-type: none"> <li>• Push the needle <b>straight</b> onto the pen.</li> <li>• Turn until it is on <b>tight</b>.</li> </ul>		
<p><b>The needle is covered by two caps. You must remove both caps.</b> If you forget to remove both caps, you will <b>not</b> inject any solution.</p> <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. <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>		
<p><b>2. Check the flow with each new pen</b></p>		
<ul style="list-style-type: none"> <li>• If your pen is already in use, go to step 3 'Select your dose'. Only check the flow before your <b>first injection with each new pen</b>.</li> <li>• Turn the dose selector <b>to the flow check symbol</b> (  ) right past '0'. Make sure the flow check symbol lines up with the pointer.</li> </ul>		

	 <p>Flow check symbol selected</p>
<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. <b>If no drop appears</b>, 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.</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. 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> 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>	
<ul style="list-style-type: none"> <li><b>Turn the dose selector to select 2 mg.</b> Keep turning until the dose counter stops and shows 2 mg.</li> </ul>	 <p>2 mg selected</p>
<p>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.</p>	
<p><b>⚠ Always use the dose counter and the dose pointer to see that 2 mg has been selected before injecting this medicine.</b> <b>Do not count the pen clicks.</b> <b>Only doses of 2 mg must be selected with the dose selector.</b> 2 mg 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 2, <b>at least 2 mg</b> is left in your pen. If the <b>dose counter stops before 2 mg</b>, there is not enough solution left for a full dose of 2 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>Watch as the dose counter returns to 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>Continue pressing the dose button while keeping the needle in your skin. <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. You can then release the dose button.</b> If blood appears at the injection site, press lightly. Hold the dose button down until the dose counter returns to '0'.</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> </ul>	



<ul style="list-style-type: none"> <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>	
<b>5. After your injection</b>	
<p><b>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.</b></p> <p>Unscrew the needle and dispose of it carefully <b>as instructed by your doctor, nurse, pharmacist or local authorities.</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>	
<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> <li>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.</li> </ul>	
<p><b>Caring for your pen</b></p> <p>Treat your pen with care. Rough handling or misuse may cause inaccurate dosing, which may lead to high blood sugar levels or abdominal discomfort such as nausea or vomiting.</p>	

- **Do not leave the pen in a car** or another place where it can get too hot or too cold.
- **Do not inject Ozempic® which has been frozen.** If you do that, your blood sugar level may get too high or you might feel abdominal discomfort such as nausea or vomiting.
- **Do not inject Ozempic® which has been exposed to direct sunlight.** If you do that, your blood sugar level may get too high.
- **Do not expose your pen to dust, dirt or liquid.**
- **Do not wash, soak or lubricate your pen.** 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.