

## Package leaflet: Information for the patient

### Ozempic® 0.5 mg solution for injection in pre-filled pen semaglutide

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

#### **Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

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

#### **What is in this leaflet**

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

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

Ozempic® contains the active substance semaglutide. It helps your body reduce your blood sugar level only when blood sugar is too high and can help prevent heart disease.

Ozempic® is used:

- on its own – if your blood sugar is not controlled well enough by diet and exercise alone, and you cannot use metformin (another diabetes medicine) or
- with other medicines for diabetes – when they are not enough to control your blood sugar levels. These other medicines may include: oral antidiabetics (such as metformin, thiazolidinediones, sulfonylureas, sodium-glucose cotransporter 2 (SGLT2) inhibitor) or insulin.

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

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

##### **Do not use Ozempic®**

- if you are allergic to semaglutide or any of the other ingredients of this medicine (listed in section 6).

##### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before using this medicine.

This medicine is not an insulin and should not be used if:

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

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

### **Effects on the digestive system**

During treatment with this medicine, you may feel sick (nausea) or be sick (vomiting), or have diarrhoea. These side effects can cause dehydration (loss of fluids). It is important that you drink plenty of fluids to prevent dehydration. This is especially important if you have kidney problems. Talk to your doctor if you have any questions or concerns.

### **Severe and on-going stomach pain which could be due to acute pancreatitis**

If you have 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). Please see section 4 for the warning signs of inflamed pancreas.

### **Hypoglycaemia**

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

### **Diabetic eye disease (retinopathy)**

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

### **Children and adolescents**

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

### **Other medicines and Ozempic®**

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

In particular, tell your doctor, pharmacist or nurse if you are using medicines containing any of the following:

- Warfarin or other similar medicines taken by mouth to reduce blood clotting (oral anti-coagulants). Frequent blood testing to determine the ability of your blood to clot may be required.
- If you are using insulin, your doctor will tell you how to reduce the dose of insulin and will recommend you to monitor your blood sugar more frequently, in order to avoid hyperglycaemia (high blood sugar) and diabetic ketoacidosis (a complication of diabetes that occurs when the body is unable to break down glucose because there is not enough insulin).

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

If you are pregnant or breast-feeding, think you might be pregnant, or are planning to have a baby, ask your doctor for advice before taking this medicine.

This medicine should not be used during pregnancy, as it is not known if it may affect your unborn child. Therefore, it is recommended to use contraception while using this medicine. If you wish to become pregnant, you should stop using this medicine at least two months in advance. If you become pregnant when using this medicine, talk to your doctor right away, as your treatment will need to be changed.

Do not use this medicine if you are breast-feeding, as it is unknown if it passes into breast milk.

### **Driving and using machines**

Ozempic® is unlikely to affect your ability to drive and use machines. If you use this medicine in combination with a sulphonylurea or insulin, low blood sugar (hypoglycaemia) may occur which may reduce your ability to concentrate. Avoid driving or using machines if you get any signs of low blood sugar. See section 2, 'Warnings and precautions' for information on increased risk of low blood sugar and section 4 for the warning signs of low blood sugar. Talk to your doctor for further information.

### **Sodium content**

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

## **3. How to use Ozempic®**

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

### **How much to use**

- The starting dose is 0.25 mg once a week for four weeks.
- After four weeks your doctor will increase your dose to 0.5 mg once a week.
- Your doctor may increase your dose to 1 mg once a week if your blood sugar is not controlled well enough with a dose of 0.5 mg once a week.
- Your doctor may increase your dose to 2 mg once a week if your blood sugar is not controlled well enough with a dose of 1 mg once a week.

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

### **How Ozempic® is given**

Ozempic® is given as an injection under the skin (subcutaneous injection). Do not inject it into a vein or muscle.

- The best places to give the injection are the front of your thighs, the front of your waist (abdomen), or your upper arm.
- Before you use the pen for the first time, your doctor or nurse will show you how to use it.

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

### **When to use Ozempic®**

- You should use this medicine once a week on the same day each week if possible.
- You can give yourself the injection at any time of the day – regardless of meals.

To help you remember to inject this medicine once a week only, it is recommended to note the chosen weekday (e.g. Wednesday) on the carton and to write the date on the carton every time you have injected it.

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

**If you use more Ozempic® than you should**

If you use more Ozempic® than you should, talk to your doctor straight away. You may get side effects such as feeling sick (nausea).

**If you forget to use Ozempic®**

If you forgot to inject a dose and:

- it is 5 days or less since you should have used Ozempic®, use it as soon as you remember. Then inject your next dose as usual on your scheduled day.
- it is more than 5 days since you should have used Ozempic®, skip the missed dose. Then inject your next dose as usual on your scheduled day.

Do not use a double dose to make up for a forgotten dose.

**If you stop using Ozempic®**

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

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

**4. Possible side effects**

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

**Serious side effects**

**Common** (may affect up to 1 in 10 people)

- complications of diabetic eye disease (retinopathy) – you should inform your doctor if you experience eye problems, such as changes in vision, during treatment with this medicine.

**Uncommon** (may affect up to 1 in 100 people)

- Inflamed pancreas (acute pancreatitis) which could cause severe pain in the stomach and back which does not go away. You should see a doctor immediately if you experience such symptoms.

**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.

**Other side effects**

**Very common** (may affect more than 1 in 10 people)

- feeling sick (nausea) – this usually goes away over time
- diarrhoea – this usually goes away over time

**Common** (may affect up to 1 in 10 people)

- being sick (vomiting)
- low blood sugar (hypoglycaemia) when this medicine is used with another antidiabetic medicine

The warning signs of low blood sugar may come on suddenly. They can include: cold sweat, cool pale skin, headache, fast heartbeat, feeling sick (nausea) or very hungry, changes in vision, feeling sleepy or weak, feeling nervous, anxious or confused, difficulty concentrating or shaking.

Your doctor will tell you how to treat low blood sugar and what to do if you notice these warning signs.

Low blood sugar is more likely to happen if you also take a sulfonylurea or insulin. Your doctor may reduce your dose of these medicines before you start using this medicine.

- indigestion
- inflamed stomach ('gastritis') – the signs include stomach ache, feeling sick (nausea) or being sick (vomiting)
- reflux or heartburn – also called 'gastro-esophageal reflux disease' (GERD)
- stomach pain
- bloating of the stomach
- constipation
- burping
- gall stones
- dizziness
- tiredness
- weight loss
- less appetite
- gas (flatulence)
- increase of pancreatic enzymes (such as lipase and amylase).

**Uncommon** (may affect up to 1 in 100 people)

- change in the way food or drink tastes
- fast pulse
- injection site reactions – such as bruising, pain, irritation, itching and rash
- allergic reactions like rash, itching or hives
- a delay in the emptying of the stomach.

### **Reporting of side effects**

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

### **Great Britain:**

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Ozempic®**

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

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

### **Before opening:**

Store in a refrigerator (2 °C–8 °C). Do not freeze. Keep away from the cooling element. Protect from light.

**During use:**

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

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information****What Ozempic® contains**

- The active substance is semaglutide. One ml solution for injection contains 1.34 mg semaglutide. One pre-filled pen contains 2 mg semaglutide in 1.5 ml solution. Each dose contains 0.5 mg of semaglutide in 0.37 ml.
- The other ingredients are: disodium phosphate dihydrate, propylene glycol, phenol, water for injections, sodium hydroxide/hydrochloric acid (for pH adjustment). See also section 2, 'Sodium content'.

**What Ozempic® looks like and contents of the pack**

Ozempic® is a clear and colourless or almost colourless solution for injection in a pre-filled pen. Each pre-filled pen contains 1.5 ml of solution, delivering 4 doses of 0.5 mg.

**Ozempic® 0.5 mg solution for injection is available in the following pack sizes:**

1 pen and 4 disposable NovoFine® Plus needles.  
3 pens and 12 disposable NovoFine® Plus needles.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

Novo Nordisk A/S  
Novo Allé  
DK-2880 Bagsværd  
Denmark

**This leaflet was last revised in 04/2023**

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## Instructions on how to use Ozempic® 0.5 mg 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® 0.5 mg**, then look at the illustrations below to get to know the different parts of your pen and needle.

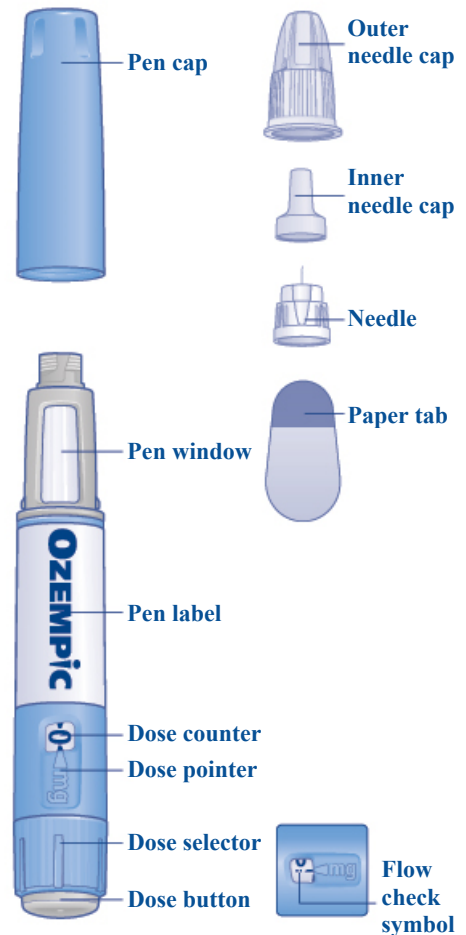
**If you are blind or have poor eyesight and cannot read the dose counter on the pen, do not use this pen without help.**

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

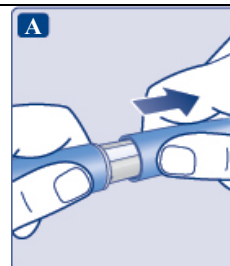
NovoFine® Plus needles are included in the pack.

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

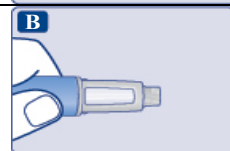


#### 1. Prepare your pen with a new needle

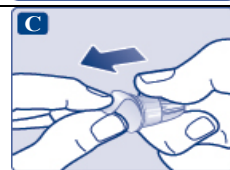
- **Check the name and coloured label** of your pen, to make sure that it contains Ozempic®. This is especially important if you take more than one type of injectable medicine. Using the wrong medicine could cause severe harm to your health.
- **Pull off the pen cap.**

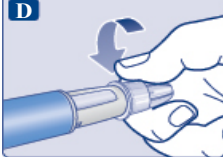
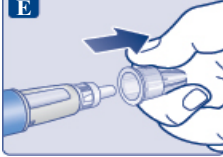
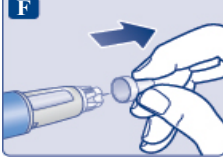

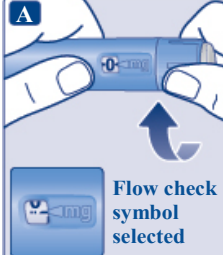



- **Check that the solution in your pen is clear** and colourless. Look through the pen window. If the solution looks cloudy or coloured, do not use the pen.



- **Take a new needle.** Check the paper tab and the outer needle cap for damages that could affect sterility. If any damage is seen use a new needle.
- **Tear off the paper tab.**



<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 reduces the risk of 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 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. <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. <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. 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>	



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

### 3. Select your dose

- **Turn the dose selector to select 0.5 mg.**  
Keep turning until the dose counter stops and shows 0.5 mg.



Only the dose counter and dose pointer will show that 0.5 mg has been selected.  
The dose selector clicks differently when turned forwards, backwards or past 0.5 mg. Do not count the pen clicks.

- ⚠ **Always use the dose counter and the dose pointer to see that 0.5 mg has been selected before injecting this medicine.**  
Do not count the pen clicks.  
0.5 mg in the dose counter must line up precisely with the dose pointer to ensure that you get a correct dose.

### How much solution is left

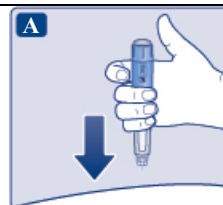
- **To see how much solution is left, use the dose counter:**  
Turn the dose selector until the **dose counter stops**. If it shows 0.5, **at least 0.5 mg** is left in your pen.  
If the **dose counter stops before 0.5 mg**, there is not enough solution left for a full dose of 0.5 mg.



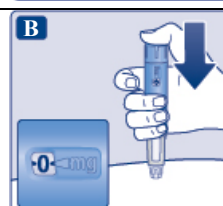
- ⚠ If there is not enough solution left in your pen for a full dose, do not use it. Use a new Ozempic® pen.

### 4. Inject your dose

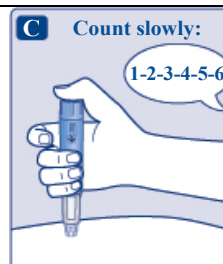
- **Insert the needle into your skin** as your doctor or nurse has shown you.
- **Make sure you can see the dose counter.** Do not cover it with your fingers. This could interrupt the injection.

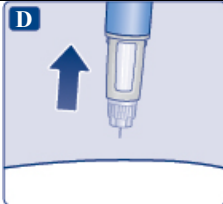
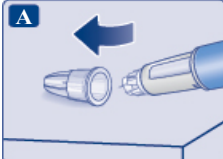
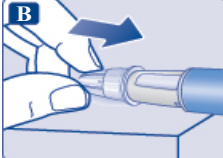
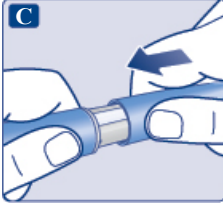


- **Press and hold down the dose button until the dose counter shows 0.** The 0 must line up with the dose pointer. You may then hear or feel a click.



- **Keep the needle in your skin** after the dose counter has returned to 0 and **count slowly to 6**. This is to make sure that you get your full dose.
- 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.



<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 in accordance with local guidelines. Ask your doctor, nurse or pharmacist about sharps disposal.</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> This reduces the risk of 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>	

Treat your pen with care. Rough handling or misuse may cause inaccurate dosing. If this happens you might not get the intended effect of this medicine.

- **Do not inject Ozempic® which has been frozen.** If you do that, you might not get the intended effect of this medicine.
- **Do not inject Ozempic® which has been exposed to direct sunlight.** If you do that, you might not get the intended effect of this medicine.
- **Do not expose your pen to dust, dirt or liquid.**
- **Do not wash, soak or lubricate your pen.** 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.

## **Annex IV**

### **Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)**

### **Scientific conclusions**

Taking into account the PRAC Assessment Report on the PSUR(s) for semaglutide, the scientific conclusions of CHMP are as follows:

In view of the available data on dysgeusia from clinical trials and spontaneous reports, the PRAC considers a causal relationship between semaglutide p.o. (Rybelsus) and dysgeusia is at least a reasonable possibility. The PRAC concluded that the product information of products containing oral semaglutide (Rybelsus) should be amended accordingly.

In view of the available data on delayed gastric emptying from clinical trials, the PRAC considers a causal relationship between semaglutide (Ozempic®, Rybelsus and Wegovy) and delayed gastric emptying is at least a reasonable possibility. The PRAC concluded that the product information of products containing semaglutide should be amended accordingly.

The CHMP agrees with the scientific conclusions made by the PRAC.

### **Grounds for the variation to the terms of the marketing authorisation(s)**

On the basis of the scientific conclusions for semaglutide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing semaglutide is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.