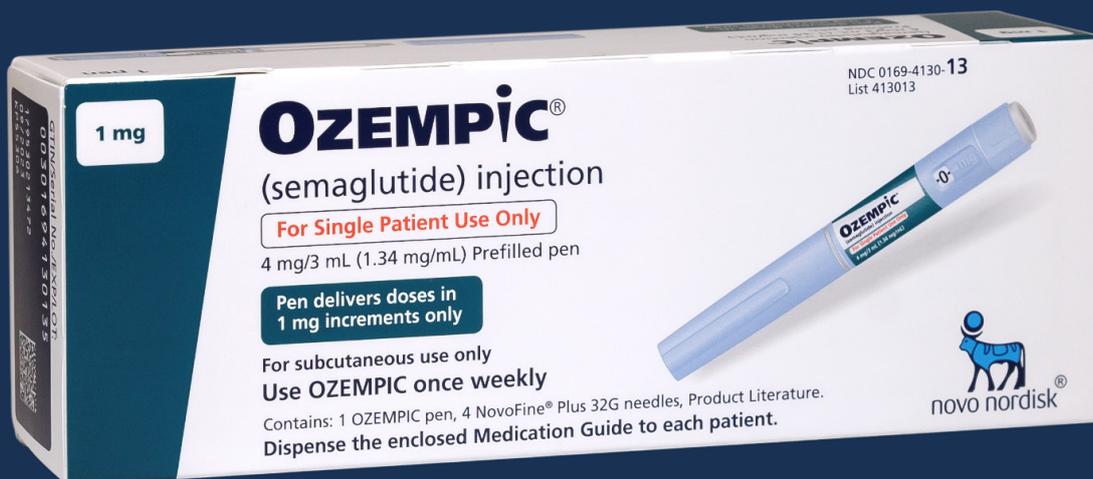




OZEMPIC®

INSTRUCTIONS GUIDE



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

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 –

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 0.25 mg of semaglutide in 0.19 ml. •

The other ingredients are: disodium phosphate dihydrate, propylene glycol, phenol, water for injections, sodium hydroxide/hydrochloric acid (for pH adjustment)

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.

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).

Hypoglycaemia

Combining a sulfonylurea or an insulin with this medicine might increase the risk of getting low blood sugar levels (hypoglycaemia).

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

Avoid driving or using Approved 05/2018 [UK/IE] machines if you get any signs of low blood sugar.

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. 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 anticoagulants). Frequent blood testing to determine the ability of your blood to clot may be required.

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 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.

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. Rare: may affect up to 1 in 1,000 people
- severe allergic reactions (anaphylactic reactions). You should seek immediate medical help and inform your doctor straight away if you get symptoms such as breathing problems, swelling of face and throat 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

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

When you start to use your medication:

- WEEK 1 – TYPICALLY WE START ON 0.25MG DOSE – THIS CAN BE ACHIEVED BY TURNING THE DOSE COUNTER 18 GENTLE CLICKS
- **AFTER WEEK 1 PLEASE CONTACT YOUR NURSE FOR AN UPDATE – AND TO OBTAIN YOUR SECOND DOSE RECOMMENDATIONS – YOUR NURSES PRIVATE MOBILE IS 07706406592**
- WE REQUEST THAT YOU MAINTAIN CONTACT WITH YOUR NURSE MINIMUM ONCE PER WEEK
- WE OFFER A WALK IN WEIGHT LOSS SERVICE: INCLUDING WEIGHT AND WAIST CIRCUMFERENCE MEASUREMENTS

USUAL DOSE RECOMMENDATIONS:

FIRST PEN PRESCRIBED IN A 0.5MG PEN

WEEK 1: 0.25MG WHICH IS 18 CLICKS

WEEK 2: 0.25MG WHICH IS 18 CLICKS

WEEK 3: 0.5MG WHICH IS 36 CLICKS WHICH IS VISIBLE IN THE PENS WINDOW

WEEK 4: 0.5MG WHICH IS 36 CLICKS WHICH IS VISIBLE IN THE PENS WINDOW

WEEK 5: 0.5MG WHICH IS 36 CLICKS WHICH IS VISIBLE IN THE PENS WINDOW

SECOND PEN PRESCRIBED IS A 1MG PEN

WEEK 1: 1MG WHICH IS VISIBLE IN THE PENS WINDOW

WEEK 2: 1MG WHICH IS VISIBLE IN THE PENS WINDOW

WEEK 3: 1MG WHICH IS VISIBLE IN THE PENS WINDOW

WEEK 4: 1MG WHICH IS VISIBLE IN THE PENS WINDOW

Ozempic® pre-filled pen and needle (example)

