



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/849609/2017  
EMA/H/C/004174

## EPAR summary for the public

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# Ozempic

## semaglutide

This is a summary of the European public assessment report (EPAR) for Ozempic. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Ozempic.

For practical information about using Ozempic, patients should read the package leaflet or contact their doctor or pharmacist.

### What is Ozempic and what is it used for?

Ozempic is a diabetes medicine used with diet and exercise to treat adults whose type 2 diabetes is not satisfactorily controlled.

Ozempic can be used on its own in patients who cannot take metformin (another diabetes medicine). It can also be used as an 'add-on' to other diabetes medicines.

Ozempic contains the active substance semaglutide.

### How is Ozempic used?

Ozempic is available as a solution for injection in prefilled pens and can only be obtained with a prescription. It is injected under the skin of the belly, the thigh or the upper arm.

The starting dose of Ozempic is 0.25 mg once a week. After four weeks, this dose should be increased to 0.5 mg. If needed, the dose can be further increased up to a maximum of 1 mg once a week. For further information, see the package leaflet.



## **How does Ozempic work?**

The active substance in Ozempic, semaglutide, is a 'GLP-1 receptor agonist'. It acts in the same way as GLP-1 (a hormone produced in the gut) by increasing the amount of insulin that the pancreas releases in response to food. This helps with the control of blood glucose levels.

## **What benefits of Ozempic have been shown in studies?**

Studies showed that Ozempic is effective at lowering blood glucose levels and reducing the risk of health complications in patients with type 2 diabetes.

Five studies in over 4,000 patients showed that Ozempic lowered levels of HbA1c (a measure of blood glucose) by between 1.2 and 1.8 percentage points over 10 to 13 months. Ozempic in these studies compared favourably with other treatments, sitagliptin, exenatide and insulin glargine (which led to reductions of 0.55, 0.92, 0.83 percentage points respectively) and placebo (reductions of up to 0.09 percentage points). In addition, the results indicated that treatment with Ozempic was associated with a beneficial fall in body weight.

A further study in over 3,000 diabetes patients at high risk of heart problems showed that overall, heart attack, stroke or death occurred less frequently in patients treated with Ozempic (6.6%) than with placebo (8.9%). When looking at the three 'events' separately, fewer patients taking Ozempic had a heart attack or stroke, but rates of death from heart problems were similar in the two groups.

## **What are the risks associated with Ozempic?**

The most common side effects with Ozempic (which may affect more than 1 in 10 people) include problems with the digestive system, such as diarrhoea, vomiting and nausea (feeling sick). These are mild or moderate in severity and of short duration. Serious worsening of diabetic retinopathy (damage to the retina, the light sensitive membrane at the back of the eye) is common (it may affect up to 1 in 10 people).

For the full list of all side effects and restrictions with Ozempic, see the package leaflet.

## **Why is Ozempic approved?**

Ozempic was shown to be effective at controlling blood glucose levels. Treatment with Ozempic also led to weight loss, which is considered beneficial in patients with diabetes. Ozempic was also shown to be effective at reducing the occurrence of serious health complications associated with diabetes such as heart attack and stroke.

Regarding safety, this was considered in line with that of other medicines of the same class. Side effects affecting the digestive system are considered to be manageable. Worsening of diabetic retinopathy has also been observed and will be further investigated.

The European Medicines Agency concluded that the benefits of Ozempic seen in studies outweighed its risk and recommended it be approved for use in the EU.

## **What measures are being taken to ensure the safe and effective use of Ozempic?**

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Ozempic have been included in the summary of product characteristics and the package leaflet.

## Other information about Ozempic

The European Commission granted a marketing authorisation valid throughout the European Union for Ozempic on 8 February 2018.

The full EPAR for Ozempic can be found on the Agency's website: [ema.europa.eu/Find/medicine/Human medicines/European public assessment reports](http://ema.europa.eu/Find/medicine/Human%20medicines/European%20public%20assessment%20reports). For more information about treatment with Ozempic, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 02-2018.