



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

26 July 2024  
EMA/340123/2024  
EMA/H/C/005422/II/0017

## Outcome of assessment to extend the use of Wegovy (semaglutide)

The European Medicines Agency has finalised its assessment of an application to extend the indication of the medicine Wegovy to include prevention of major cardiovascular (heart and blood circulation) problems (non-fatal heart attack, stroke or death from heart and circulation problems) in adults with established cardiovascular disease and a BMI (body mass index) of at least 27 kg/m<sup>2</sup>.

EMA did not agree on granting a separate indication for prevention, but the medicine's product information will be updated to include the study results submitted for the application so that healthcare professionals have access to up-to-date data on the effects of Wegovy in people with established cardiovascular disease and a BMI of 27 kg/m<sup>2</sup> or greater.

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

Wegovy is a medicine used together with diet and physical activity to help people to lose weight and keep their weight under control. It is used in adults who have:

- a BMI of 30 kg/m<sup>2</sup> or greater (obesity) or;
- a BMI of at least 27 kg/m<sup>2</sup> but less than 30 kg/m<sup>2</sup> (overweight) who have weight-related health problems (such as diabetes, high blood pressure, abnormal levels of fats in the blood, breathing problems during sleep called 'obstructive sleep apnoea' or a history of heart attack, stroke or blood vessel problems).

It is also used in adolescents from 12 years of age whose BMI is at or above the 95<sup>th</sup> percentile for their age and gender (obesity) and who weigh more than 60 kg.

BMI is a measure of weight in relation to height. A BMI at the 95<sup>th</sup> percentile means that it is greater than that of 95% of people of the same age and gender.

Wegovy has been authorised in the EU since January 2022. It contains the active substance semaglutide and is available as pre-filled pens containing a solution for injection. It is injected once a week under the skin in the belly, thigh or upper arm.

Further information on Wegovy's current uses can be found on the Agency's website:

<https://www.ema.europa.eu/en/medicines/human/EPAR/wegovy>

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## **What change had the company applied for?**

The company applied for a separate indication for Wegovy to reduce the risk of major heart and circulation problems in adults with a history of serious cardiovascular disease (such as a heart attack, stroke or poor blood flow to the limbs) and a BMI of 27 kg/m<sup>2</sup> or greater.

## **How does Wegovy work?**

The active substance in Wegovy, semaglutide, is a glucagon-like peptide-1 (GLP-1) receptor agonist. It acts in the same way as GLP-1 (a natural hormone in the body) and, among other things, regulates appetite by increasing a person's feelings of fullness, while reducing their food intake, hunger and cravings.

## **What did the company present to support its application?**

The company presented data from a main study involving 17,604 patients, aged 45 years and over with a BMI of 27 kg/m<sup>2</sup> or greater. Patients had established signs of heart disease such as a previous heart attack or stroke or narrowing of the peripheral arteries (arteries that carry blood from the heart to the legs, arms and other parts of the body) but did not have diabetes. Patients were divided into two groups and followed for more than 3 years. In one group patients received Wegovy with standard of care (treatment that medical experts consider most appropriate); in the other group patients received placebo (dummy treatment) with standard of care. The study looked at the occurrence of non-fatal heart attack, stroke or deaths from heart and circulation problems in the two groups.

## **What were EMA's conclusions?**

Based on the results of the main study EMA's human medicines committee (CHMP) acknowledges that Wegovy reduces major cardiovascular events in people with established cardiovascular disease and a BMI of 27 kg/m<sup>2</sup> or greater. The CHMP considered that the use of Wegovy in this group of people is already covered by the approved indication for weight management in people with a BMI of 27 kg/m<sup>2</sup> or greater. Therefore, no separate indication for the prevention of cardiovascular disease in people with obesity and overweight is needed.