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Wegovy (*semaglutide*)

An overview of Wegovy and why it is authorised in the EU

What is Wegovy and what is it used for?

Wegovy is 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/m² or greater (obesity) or
- a BMI of at least 27 kg/m² but less than 30 kg/m² (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 95th percentile for their age and gender (obesity) and who weigh more than 60 kg.

BMI (body mass index) is a measure of your weight in relation to your height. A BMI at the 95th percentile means that it is greater than that of 95% of people of the same age and gender.

Wegovy contains the active substance semaglutide.

How is Wegovy used?

Wegovy 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.

To reduce the risk of symptoms affecting the gut, the weekly dose is gradually increased over 16 weeks.

Patients can administer the medicine themselves.

The medicine can only be obtained with a prescription. For more information about using Wegovy, see the package leaflet or contact your healthcare provider.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

How does Wegovy work?

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

What benefits of Wegovy have been shown in studies?

Studies have shown that Wegovy is effective in helping people lose weight, with a significant proportion of them achieving at least a 5% weight reduction.

Three of the studies involved adults who had tried unsuccessfully to lose weight in the past and had a BMI of ≥30 kg/m^2 or a BMI of ≥27 kg/m^2 plus a weight-related health problem.

In the first of these, involving 1,961 people, people treated with Wegovy were able to lose on average 15% of their body weight after 68 weeks compared with a 2% loss of weight in people who had placebo (a dummy treatment). In addition, 84% of people in the Wegovy group were able to lose at least 5% of their weight compared with 31% of people in the placebo group.

In the second study, involving 611 people, those treated with Wegovy lost on average 16% of their body weight after 68 weeks compared with a 6% loss of weight in people who had placebo. Around 85% of people in the Wegovy group lost at least 5% of their weight compared with 48% of people in the placebo group. All participants in this study also received counselling to help them lose weight.

The third study, involving 902 people, looked at how the effects of Wegovy were maintained over the first 20 weeks. In this study, all participants had Wegovy for 20 weeks, after which some were stopped having Wegovy and were given placebo instead. After 48 more weeks, those who continued on Wegovy lost a further 8% of their body weight while those on placebo regained 7% of theirs, indicating that people need to continue taking Wegovy in order not to regain weight.

A fourth study involved 1,210 adults with type 2 diabetes with a BMI of ≥27 kg/m^2 and who had also tried unsuccessfully to lose weight in the past. After 68 weeks, those treated with Wegovy were able on average to lose 10% of their weight compared with a 3% loss in people who had placebo. In addition, 67% of people in the Wegovy group were able to lose at least 5% of their weight compared with 30% of people in the placebo group.

Another study involved 200 adolescents aged 12 to less than 18 years with a BMI at or above the 95th percentile (obesity) and 1 with a BMI at or above the 85th percentile (overweight) and at least one weight-related health problem. The study found that after 68 weeks, BMI dropped by an average of 16% in those treated with Wegovy compared with an average increase of less than 1% in those who received placebo. Around 73% of those who received Wegovy lost at least 5% of their weight compared with around 18% of those who received placebo.

What are the risks associated with Wegovy?

The most common side effects with Wegovy (which may affect more than 1 in 10 people) are headache, nausea (feeling sick), vomiting, diarrhoea, constipations and abdominal (belly) pain.

For the full list of side effects and restrictions of Wegovy, see the package leaflet.

Why is Wegovy authorised in the EU?

Obesity can lead to severe health problems and many people with obesity experience difficulty trying to lose weight. Wegovy is effective at reducing weight in adults with obesity or who are overweight

with a weight-related health problem. It is also effective in adolescents with obesity, but there were not enough data on overweight adolescents.

The medicine's side effects are considered manageable. However, to prevent unnecessary long-term treatment, treatment should be stopped if adolescents do not achieve a weight loss of at least 5% within 12 weeks on the maximum dose or maximum tolerated dose.

The European Medicines Agency therefore decided that Wegovy's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Wegovy?

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

As for all medicines, data on the use of Wegovy are continuously monitored. Suspected side effects reported with Wegovy are carefully evaluated and any necessary action taken to protect patients.

Other information about Wegovy

Wegovy received a marketing authorisation valid throughout the EU on 6 January 2022.

Further information on Wegovy can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/wegovy

This overview was last updated in 04-2023.