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Saxenda (*liraglutide*)

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

What is Saxenda and what is it used for?

Saxenda is a medicine used along with diet and increased physical activity to help manage weight in:

- adults with obesity (BMI of 30 or more);
- adults with overweight (BMI between 27 and 30) and weight-related complications such as diabetes, abnormally high levels of fat in the blood, high blood pressure or obstructive sleep apnoea (frequent interruption of breathing during sleep);
- adolescents from 12 years of age with obesity (BMI of 30 or more for adults by international age and gender related cut-off points) who weigh more than 60 kg;
- children from 6 to less than 12 years of age with obesity (BMI at or above the 95th percentile) who weigh at least 45 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.

Saxenda contains the active substance liraglutide.

How is Saxenda used?

Saxenda can only be obtained with a prescription. In children from 6 to less than 12 years old, treatment with Saxenda should be started by a doctor experienced in the treatment of children with obesity.

Saxenda is given as an injection with a pre-filled pen once per day under the skin in the thigh, upper arm or belly. The dose is slowly increased over 4 weeks.

Treatment with Saxenda should be stopped if patients have not lost at least 4% (for adolescents and children from 6 years of age) or 5% (for adults) of their initial body weight after 12 weeks of treatment at the maximum dose or the maximum tolerated dose. Once a year the doctor should re-assess the need to continue treatment.

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For more information about using Saxenda, see the package leaflet or contact your doctor or pharmacist.

How does Saxenda work?

The active substance in Saxenda, liraglutide, is a glucagon-like peptide-1 (GLP-1) receptor agonist. The active substance in Saxenda, liraglutide, acts in the same way as GLP-1 (a natural hormone in the body), which regulates appetite. By attaching to receptors (targets) for GLP-1 in brain cells, liraglutide is thought to cause a feeling of fullness, lowering hunger and food cravings. This helps a person to reduce their food intake.

What benefits of Saxenda have been shown in studies?

Saxenda has been shown to be effective at reducing body weight in 5 main studies involving over 5,800 adults who had obesity or overweight. The studies lasted up to 56 weeks and compared Saxenda with placebo (a dummy treatment). Patients in the studies were given the medicine as part of a weight loss programme involving counselling and advice on diet and physical activity.

Looking at the results of the 5 studies together, Saxenda, given at the maximum recommended dose, led to a 7.5% reduction in body weight, compared with a 2.3% reduction in patients taking placebo. Patients treated with Saxenda had a continuous decrease in body weight during the first 40 weeks of treatment, after which the weight loss achieved was maintained. Weight loss was more pronounced in women than in men. When the figures for the main studies were re-analysed using a more conservative method that assumed that patients who did not complete the study (around 30%) would not have seen any improvement, similar but smaller weight reductions with Saxenda were noted.

Another study involved 251 adolescents aged 12 to less than 18 years with a BMI of 30 or more (for adults by international age and gender related cut-off points). The study found that after 56 weeks, the BMI standard deviation score was reduced by 0.23 points in those treated with Saxenda compared with no change in those who received placebo. BMI was reduced by at least 5% in around 43% of patients who received Saxenda compared with around 19% of those who received placebo. Patients who took Saxenda lost on average around 2 kg of weight while those who took placebo gained around 2 kg.

A further study involved 82 children aged 6 to less than 12 years with a BMI at or above the 95th percentile for their age and gender. The study found that after 56 weeks, BMI was reduced by 5.8% in children treated with Saxenda compared with an increase of 1.6% in those given placebo. BMI was reduced by at least 5% in around 46% of children who received Saxenda compared with around 9% of those who received placebo. Children who took Saxenda gained on average around 2% of their initial weight while those who took placebo gained around 10% of their initial weight.

What are the risks associated with Saxenda?

For the complete list of side effects and restrictions with Saxenda, see the package leaflet.

The most common side effects with Saxenda (which may affect more than 1 in 10 people) include nausea (feeling sick), vomiting, diarrhoea and constipation.

Why is Saxenda authorised in the EU?

The European Medicines Agency decided that Saxenda's benefits are greater than its risks and it can be authorised for use in the EU. The Agency considered that Saxenda has a modest (particularly in

men) but still clinically relevant effect on weight loss in adults. In children from 6 years of age and adolescents, Saxenda was shown to reduce BMI for the majority of patients, although it is not clear whether this will translate into health improvement.

It is recommended to stop treatment after 12 weeks if the reduction in weight or BMI is not sufficient. Regarding safety, the most common side effects with Saxenda relate to the stomach and gut, such as nausea, which are more frequent in children than in adolescents and adults. To limit these effects, the dose of Saxenda is slowly increased over 4 weeks when starting treatment.

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

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

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

Other information about Saxenda

Saxenda received a marketing authorisation valid throughout the EU on 23 March 2015.

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

This overview was last updated in 06-2025.