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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 who have obesity (BMI of 30 or more);
- adults who are overweight (BMI between 27 and 30) and have 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) who weigh more than 60 kg.

BMI (body mass index) is a measure of your weight in relation to your height.

Saxenda contains the active substance liraglutide.

How is Saxenda used?

Saxenda is available as a solution for injection in a pre-filled pen.

Saxenda is injected once per day, preferably at the same time every day. It is given as an injection 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) 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.

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

How does Saxenda work?

The active substance in Saxenda, liraglutide, is a glucagon-like peptide-1 (GLP-1) receptor agonist. The exact way that Saxenda works in weight loss is not fully understood, but it appears to act on the

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parts of the brain that regulate appetite, by attaching to GLP-1 receptors in brain cells and thereby increasing feelings of fullness and lowering feelings of hunger.

Liraglutide is also used at lower doses for the treatment of type 2 diabetes in the authorised medicine Victoza.

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 were 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. 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.

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 adolescents from 12 years of age, Saxenda was shown to have an effect on weight loss for the majority of patients, although it is not clear whether this will translate into health improvement. For both adults and adolescents, it is recommended to stop treatment after 12 weeks if the weight loss is not sufficient. Regarding safety, the most common side effects with Saxenda relate to the stomach and gut such as nausea. To limit these effects, when starting treatment the dose of Saxenda is slowly increased over 4 weeks.

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

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