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EPAR summary for the public

Saxenda

liraglutide

This is a summary of the European public assessment report (EPAR) for Saxenda. 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 Saxenda.

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

What is Saxenda and what is it used for?

Saxenda is a medicine used along with diet and exercise to help manage weight in adults:

- who are obese (have a body-mass index – BMI – of 30 or more);
- who are overweight (have a 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).

BMI is a measurement that indicates body weight relative to height.

Saxenda contains the active substance liraglutide.

How is Saxenda used?

Saxenda is available as a solution for injection in pre-filled pens. The medicine can only be obtained with a prescription.

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 abdomen (belly). The starting dose is 0.6 mg per day. The dose is then increased each week by 0.6 mg to a maximum of 3.0 mg per day.

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Treatment with Saxenda should be stopped if patients have not lost at least 5% of their initial body weight after 12 weeks of treatment with 3 mg of Saxenda per day. The doctor should re-assess the need of continuing treatment once a year.

How does Saxenda work?

The active substance in Saxenda, liraglutide, is a 'glucagon-like peptide-1 (GLP-1) receptor agonist' that is already authorised in the EU as Victoza at lower doses (up to 1.8 mg per day) for the treatment of type 2 diabetes.

The exact way that Saxenda works in weight loss is not fully understood, but it appears to act on the 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.

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 obese or overweight patients and lasting up to 56 weeks, in which Saxenda was compared 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 exercise.

Looking at the results of the 5 studies together, Saxenda at a daily dose of 3 mg 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.

What are the risks associated with Saxenda?

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

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

Why is Saxenda approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Saxenda's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP considered that Saxenda has a modest (particularly in men) but still clinically relevant effect on weight loss. 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. Further information on the long-term safety of liraglutide (particularly its effects on the heart and blood vessels) is expected from an ongoing study with Victoza.

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

A risk management plan has been developed to ensure that Saxenda is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and

the package leaflet for Saxenda, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Saxenda

The European Commission granted a marketing authorisation valid throughout the European Union for Saxenda on 23 March 2015.

The full EPAR and risk management plan summary for Saxenda can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Saxenda, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2015.