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EPAR summary for the public

Lyxumia

lixisenatide

This is a summary of the European public assessment report (EPAR) for Lyxumia. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Lyxumia.

What is Lyxumia?

Lyxumia is a diabetes medicine that contains the active substance lixisenatide. It is available as a solution for injection in a pre-filled pen that provides either 10 micrograms or 20 micrograms of lixisenatide in each dose.

What is Lyxumia used for?

Lyxumia is used in adults who have type 2 diabetes to control their blood glucose (sugar) level. It is used together with diabetes medicines taken by mouth and/or basal insulin (long-acting insulin) in patients whose blood glucose levels are not adequately controlled by these medicines together with diet and exercise.

The medicine can only be obtained with a prescription.

How is Lyxumia used?

Lyxumia is injected once a day, in the hour before the same meal every day. It is given as an injection under the skin in the abdominal wall (at the front of the waist), upper arm or thigh. Lyxumia is started at a dose of 10 micrograms once a day which is increased to 20 micrograms once a day after 14 days.

If the patient is already taking a sulphonylurea (another diabetes medicine) or basal insulin, the doctor may need to reduce the dose of the sulphonylurea or basal insulin because there is a risk of hypoglycaemia (low blood sugar levels). Adding Lyxumia to metformin is not associated with this risk. Lyxumia should not be given with a combination of both, basal insulin and a sulphonylurea.



How does Lyxumia work?

Type 2 diabetes is a disease in which the pancreas does not make enough insulin to control the level of glucose in the blood or when the body is unable to use insulin effectively. The active substance in Lyxumia, lixisenatide, is a 'GLP-1 receptor agonist'. It works by attaching to glucagon-like peptide 1 (GLP-1) receptors that are found on the surface of the cells in the pancreas and that cause the production of insulin by the pancreas. When Lyxumia is injected, lixisenatide reaches the receptors in the pancreas and activates them. This causes the release of insulin and helps to reduce blood glucose levels and control type 2 diabetes.

How has Lyxumia been studied?

Lyxumia has been studied in seven main studies involving 3,825 adults with type 2 diabetes. Six of the studies compared Lyxumia with placebo (a dummy treatment), used alone or when added to metformin, a sulphonylurea, basal insulin, or a combination of two of these medicines, in patients in whom previous treatment had failed. In one study, Lyxumia was compared with another diabetes medicine called exenatide when added to metformin in patients whose blood sugar levels were not adequately controlled by metformin.

All of the studies measured the change in the level of glycosylated haemoglobin (HbA1c), which is the percentage of haemoglobin in the blood that has glucose attached. HbA1c gives an indication of how well the blood glucose is controlled. HbA1c levels were measured after 12 weeks when Lyxumia was used alone and after 24 weeks when it was used in combination with other diabetes medicines.

What benefit has Lyxumia shown during the studies?

Lyxumia was more effective than placebo at controlling blood glucose. When used on its own, Lyxumia reduced Hb1Ac levels by 0.6% more than placebo. When used in combination with other diabetes medicines, Lyxumia reduced Hb1Ac levels by 0.4 up to 0.9% more than placebo.

The study comparing Lyxumia with exenatide (added to metformin) showed reduced HbA1c levels by 0.79% after 24 weeks treatment with Lyxumia compared to 0.96% with exenatide twice daily.

What is the risk associated with Lyxumia?

The most common side effects with Lyxumia (seen in more than 1 patient in 10) are nausea (feeling sick), vomiting, diarrhoea and headache. These side effects were mostly mild and usually resolved over time. When used together with a sulphonylurea or basal insulin, the most common side effect (seen in more than 1 patient in 10) is hypoglycaemia (low blood glucose levels). Allergic reactions have been reported in less than 1 in 100 patients using Lyxumia.

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

Why has Lyxumia been approved?

The CHMP concluded that Lyxumia was shown to be effective at lowering blood glucose levels in patients with type 2 diabetes, when given alone or in combination with other diabetes medicines. In addition, beneficial weight loss was seen in patients treated with Lyxumia. Regarding its safety, most side effects are comparable to those of other similar diabetes medicines with side effects affecting the gut being the most common ones. The CHMP concluded that the benefits of Lyxumia outweigh its risks and recommended that it be granted marketing authorisation.

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

A risk management plan has been developed to ensure that Lyxumia 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 Lyxumia, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Lyxumia

The European Commission granted a marketing authorisation valid throughout the European Union for Lyxumia on 1 February 2013.

The full EPAR for Lyxumia can be found on the Agency's website: [ema.europa.eu/Find medicine/Human medicines/European public assessment reports](http://ema.europa.eu/Find%20medicine/Human%20medicines/European%20public%20assessment%20reports). For more information about treatment with Lyxumia, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2014.