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EPAR summary for the public

Lusduna

insulin glargine

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

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

What is Lusduna and what is it used for?

Lusduna is a medicine used in patients aged at least 2 years for the treatment of diabetes. It contains the active substance insulin glargine.

Lusduna is a 'biosimilar medicine'. This means that Lusduna is highly similar to a biological medicine (also known as the 'reference medicine') that is already authorised in the European Union (EU). The reference medicine for Lusduna is Lantus. For more information on biosimilar medicines, see the question-and-answer document here.

How is Lusduna used?

Lusduna is available in pre-filled disposable pens and can only be obtained with a prescription. It is given by injection under the skin in the belly, the thigh, or the upper arm.

Lusduna is used once a day at the same time each day. The dose of Lusduna is worked out for each patient and depends on the patient's blood glucose (sugar) level and treatment with other insulin medicines. Lusduna can also be used with diabetes medicines taken by mouth in patients who have type 2 diabetes.

For further information, see the package leaflet.

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How does Lusduna work?

Diabetes is a disease in which the level of blood sugar is high, either because the body cannot produce insulin (type 1 diabetes) or because the body does not make enough insulin or cannot use it effectively (type 2 diabetes). Lusduna is a replacement insulin that acts in the same way as the body's own insulin and helps glucose enter cells from the blood. By controlling the level of blood glucose, the symptoms of diabetes are reduced and complications are avoided.

Insulin glargine, the active substance in Lusduna, enters the bloodstream more slowly than human insulin after injection and so it works for longer.

What benefits of Lusduna have been shown in studies?

Extensive laboratory studies comparing Lusduna with Lantus have shown that insulin glargine in Lusduna is highly similar to that in Lantus in terms of chemical structure, purity and biological activity. Two additional studies showed that Lusduna is absorbed into the body and works on blood glucose in the same way as the reference medicine, Lantus.

Because Lusduna is a biosimilar medicine, studies on effectiveness and safety were not needed as these have been well established for insulin glargine.

Two supportive studies found that the effectiveness of once-daily Lusduna was comparable to Lantus. In both studies, the main measure of effectiveness was the change after 24 weeks of treatment in the level in the blood of glycosylated haemoglobin (HbA1c), a substance which indicates how well blood glucose is controlled.

In the first supportive study, involving 506 patients with type 1 diabetes, the average HbA1c score was reduced from 8.0 to 7.4% with both Lusduna and Lantus. In the second study, involving 531 patients with type 2 diabetes, the average reduction in HbA1c was from 8.3 to 7.2% with Lusduna and from 8.4 to 7.2% with Lantus.

What are the risks associated with Lusduna?

The most common side effect with Lusduna (which may affect more than 1 in 10 people) is hypoglycaemia (low blood glucose). For the full list of all side effects and restrictions with Lusduna, see the package leaflet.

Why is Lusduna approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that, in accordance with EU requirements for biosimilar medicines, Lusduna has been shown to have a comparable quality, safety and effectiveness to Lantus. Therefore, the CHMP's view was that, as for Lantus, the benefit outweighs the identified risk. The Committee recommended that Lusduna be given marketing authorisation.

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

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

Other information about Lusduna

The European Commission granted a marketing authorisation valid throughout the European Union for Lusduna on 4 January 2017.

The full EPAR for Lusduna 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 Lusduna, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2017.