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EPAR summary for the public

Lantus

insulin glargine

This document is a summary of the European Public Assessment Report (EPAR) for Lantus. 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 Lantus.

What is Lantus?

Lantus is a solution for injection that contains the active substance insulin glargine. It is available as vials, cartridges and prefilled disposable pens (OptiSet and SoloStar).

What is Lantus used for?

Lantus is used to treat diabetes in patients aged two years or older.

The medicine can only be obtained with a prescription.

How is Lantus used?

Lantus is given by injection under the skin in the abdominal wall (tummy), the thigh, or the deltoid region (shoulder). The site of injection should be changed with each injection to avoid changes to the skin (such as thickening) that can make the insulin work less well than expected. The patient's blood glucose (sugar) should be regularly tested to find the lowest effective dose.

Lantus is given once a day. In adults (aged 18 years or over), it can be given at any time, provided that it is at the same time each day. It should be given in the evening in patients aged less than 18 years. Lantus can also be given together with antidiabetes medicines taken by mouth in patients who have type 2 diabetes.

Patients can inject themselves with Lantus if they have been trained appropriately.

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How does Lantus work?

Diabetes is a disease in which the body does not produce enough insulin to control the level of blood glucose. Lantus is a replacement insulin that is very similar to the insulin made by the body.

The active substance in Lantus, insulin glargine, is produced by a method known as 'recombinant DNA technology': it is made by a bacterium that has received a gene (DNA), which makes it able to produce insulin glargine.

Insulin glargine is very slightly different from human insulin. The change means that it is absorbed more slowly and regularly by the body after an injection, and that it has a long duration of action. The replacement insulin acts in same way as naturally produced insulin and helps glucose enter cells from the blood. By controlling the level of blood glucose, the symptoms and complications of diabetes are reduced.

How has Lantus been studied?

Lantus was originally studied in 10 studies, in both type 1 diabetes (when the pancreas cannot produce insulin) and type 2 diabetes (when the body is unable to use insulin effectively). A total of 2,106 patients received Lantus in all trials combined. The main studies compared Lantus given once a day at bedtime with human insulin NPH (an intermediate-acting insulin) given once or twice a day. Injections of fast-acting insulin were also used at mealtimes. In one study, patients with type 2 diabetes also received antidiabetes medicines by mouth.

Further studies have also been carried out to compare Lantus and human insulin NPH in patients with type 1 diabetes aged between five and 18 years, 200 of whom received Lantus, and in children aged two to six years, 61 of whom received Lantus.

Studies have also been carried out in nearly 1,400 adults with type 1 or type 2 diabetes to measure the effectiveness of Lantus injected at any time during the day, compared with an injection given in the evening.

All of the studies measured the level of 'fasting' blood glucose (measured when the patients had not eaten for at least eight hours) or a substance in the blood called glycosylated haemoglobin (HbA1c), which gives an indication of how well blood glucose is controlled.

What benefit has Lantus shown during the studies?

Lantus led to a decrease in the level of HbA1c, indicating that blood glucose levels had been controlled to a similar level to that seen with human insulin. Lantus was effective in managing diabetes in adults and children aged two years and above. The effectiveness of Lantus was seen regardless of the time of the injection.

What is the risk associated with Lantus?

The most common side effect with Lantus (seen in more than 1 patient in 10) is hypoglycaemia (low blood glucose levels). Reactions at the site of the injection (redness, pain, itching and swelling) and skin reactions (rash) have been seen more often in children than in adults. For the full list of all side effects reported with Lantus, see the package leaflet.

Lantus must not be used in people who are hypersensitive (allergic) to insulin glargine or to any of the other ingredients. Lantus doses might also need to be adjusted when given with some other medicines that may have an effect on blood glucose levels. The full list is available in the package leaflet.

Why has Lantus been approved?

The CHMP decided that Lantus's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Lantus:

The European Commission granted a marketing authorisation valid throughout the European Union for Lantus on 9 June 2000.

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

This summary was last updated in 05-2012.