EMA/760389/2014
EMEA/H/C/002835

EPAR summary for the public

Abasaglar[1]

insulin glargine

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

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

What is Abasaglar and what is it used for?

Abasaglar is a medicine that contains the active substance insulin glargine. It is used in adults and children over the age of two for the treatment of diabetes.

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

How is Abasaglar used?

Abasaglar is available as cartridges and prefilled disposable pens (KwikPen) and can only be obtained with a prescription. It is given by injection under the skin in the abdominal wall (tummy), the thigh, or the deltoid region (upper arm). 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.

Abasaglar is given once a day at the same time each day. The dose is adjusted individually, and the patient's blood glucose (sugar) should be regularly tested to find the lowest effective dose. Abasaglar can also be given together with diabetes medicines taken by mouth in patients who have type-2 diabetes.

[1] Previously known as Abasria

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

For further information, see the package leaflet.

How does Abasaglar work?

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

The active substance in Abasaglar, insulin glargine, is produced by a method known as 'recombinant DNA technology': it is made by bacteria into which a gene (DNA) has been introduced that makes them able to produce insulin glargine.

Insulin glargine is 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.

What benefits of Abasaglar have been shown in studies?

Studies were carried out to show that the way Abasaglar is absorbed into the body and the way it acts on blood glucose were similar to Lantus. In addition, treatment with once-daily Abasaglar has been shown to be comparable to the reference medicine, Lantus, in two supportive studies involving a total of 1,295 adults with diabetes. In both studies, the main measure of effectiveness was the change after 6 months of treatment in the level in the blood of a substance called glycosylated haemoglobin (HbA_{1c}), which gives an indication of how well blood glucose is controlled.

- In one study, Abasaglar was compared with Lantus when added to short-acting insulin treatment in 536 patients with type 1 diabetes. Their average HbA_{1c} before treatment was 7.8% and the average fall after 6 months was similar (0.35% in the Abasaglar group and 0.46% in the Lantus group); 34.5% of those given Abasaglar, and 32.2% of those given Lantus were below the target of 7%.
- In the second study, treatment with Abasaglar or Lantus was compared in 759 patients with type 2 diabetes, as an addition to diabetes medicines taken by mouth. Average starting HbA_{1c} was 8.3%, and this fell to below 7% in 48.8% of those given Abasaglar, and 52.5% of those given Lantus, with an average percentage point fall of 1.29 and 1.34 respectively.

What are the risks associated with Abasaglar?

The most common side effect with Abasaglar (which may affect more than 1 in 10 people) is hypoglycaemia (low blood glucose). 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 and restrictions with Abasaglar, see the package leaflet.

Why is Abasaglar approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that, in accordance with EU requirements for biosimilar medicines, Abasaglar 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 Abasaglar be given marketing authorisation.

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

A risk management plan has been developed to ensure that Abasaglar 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 Abasaglar, 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 Abasaglar

The European Commission granted a marketing authorisation valid throughout the European Union for Abasria on 9 September 2014. The name of the medicine was changed to Abasaglar on 3 December 2014.

The full EPAR and risk management plan summary for Abasaglar 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 Abasaglar, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2015.