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Abasaglar[1] *(insulin glargine)*

An overview of Abasaglar and why it is authorised in the EU

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 highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Abasaglar is Lantus. For more information on biosimilar medicines, see here.

How is Abasaglar used?

Abasaglar is injected 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 injected once a day at the same time each day. The dose is adjusted according to the patient's blood glucose (sugar). Abasaglar can also be given together with diabetes medicines taken by mouth in patients who have type 2 diabetes.

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

For more information about using Abasaglar, see the package leaflet or contact your doctor or pharmacist.

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 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.

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.

[1] Previously known as Abasria

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

What benefits of Abasaglar have been shown in studies?

Laboratory studies comparing Abasaglar with Lantus have shown that the active substance in Abasaglar is highly similar to that in Lantus in terms of structure, purity and biological activity. Studies have also shown that giving Abasaglar produces similar levels of the active substance in the body to giving 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 (it fell by 0.35 percentage points in the Abasaglar group and 0.46 percentage points in the Lantus group); 34.5% of those given Abasaglar, and 32.2% of those given Lantus achieved HbA_{1c} 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.

Because Abasaglar is a biosimilar medicine, the studies on effectiveness and safety of insulin glargine carried out with Lantus do not all need to be repeated for Abasaglar

What are the risks associated with Abasaglar?

The safety of Abasaglar has been evaluated, and on the basis of all the studies carried out, the side effects of the medicine are considered to be comparable to those of the reference medicine Lantus.

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) occur more often in children than in adults. For the full list of side effects and restrictions with Abasaglar, see the package leaflet.

Why is Abasaglar approved?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Abasaglar has a highly similar structure, purity and biological activity to Lantus and is distributed in the body in the same way. In addition, studies in patients with diabetes have shown that the safety and effectiveness of Abasaglar is equivalent to that of Lantus in this condition.

All these data were considered sufficient to conclude that Abasaglar will behave in the same way as Lantus in terms of effectiveness and safety in its authorised uses. Therefore, the Agency's view was that, as for Lantus, the benefits of Abasaglar outweigh the identified risks and it can be authorised for use in the EU.

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

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

As for all medicines, data on the use of Abasaglar are continuously monitored. Side effects reported with Abasaglar are carefully evaluated and any necessary action taken to protect patients.

Other information about Abasaglar

Abasria received a marketing authorisation valid throughout the EU on 9 September 2014. The name of the medicine was changed to Abasaglar on 3 December 2014.

Further information on Abasaglar can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/abasaglar.

This overview was last updated in 09-2020.