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Ondibta (*insulin glargine*)

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

What is Ondibta and what is it used for?

Ondibta is a medicine used to treat adults, adolescents and children from 2 years of age with diabetes.

Ondibta contains the active substance insulin glargine and is a biological medicine. It is a 'biosimilar medicine'; this means that Ondibta is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Ondibta is Lantus. For more information on biosimilar medicines, see here.

How is Ondibta used?

Ondibta can only be obtained with a prescription. It is injected under the skin once a day, using a pre-filled pen, and should be taken at the same time each day.

Switching from other insulin medicines to Ondibta may require dose adjustments and close monitoring, including in patients treated with 300 units/ml insulin glargine.

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

How does Ondibta work?

Diabetes occurs when blood glucose (sugar) levels stay high, because either the body cannot make insulin (type 1 diabetes) or does not make enough insulin or cannot use it effectively (type 2 diabetes). Ondibta is a replacement insulin that acts in the same way as the body's own insulin. It helps glucose move from the blood into cells. By keeping blood glucose under control, Ondibta reduces symptoms of diabetes and prevents complications.

Insulin glargine, the active substance in Ondibta, enters the bloodstream more slowly than human insulin after injection, so it lasts longer in the body.

What benefits of Ondibta have been shown in studies?

Laboratory studies comparing Ondibta with Lantus have shown that the active substance in Ondibta is highly similar to that in Lantus in terms of structure, purity and biological activity. Studies have also

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

shown that giving Ondibta produces similar levels of the active substance in the body to those seen with Lantus.

Two studies also showed that Ondibta and Lantus have similar effectiveness. Both studies assessed changes in glycosylated haemoglobin (HbA1c), a substance which indicates how well blood glucose is controlled. The first study involved 576 people with type 1 diabetes whose condition was already under control with fast- and slow-acting insulin. The second involved 567 people with type 2 diabetes whose condition was already under control with diabetes medicines taken by mouth with or without slow-acting insulin. After 26 weeks of treatment, average HbA1c levels were similar in people given Ondibta and those given Lantus.

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

What are the risks associated with Ondibta?

The safety of Ondibta 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 Lantus.

For the complete list of side effects and restrictions of Ondibta, see the package leaflet.

The most common side effect with Ondibta (which may affect more than 1 in 10 people) is hypoglycaemia (low blood glucose levels).

Why is Ondibta authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Ondibta 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 people with type 1 or type 2 diabetes have shown that Ondibta and Lantus are equivalent in terms of safety and effectiveness.

All these data were considered sufficient to conclude that Ondibta will have the same effects as Lantus in its authorised uses. Therefore, the Agency's view was that, as for Lantus, the benefits of Ondibta 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 Ondibta?

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

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

Other information about Ondibta

Ondibta received a marketing authorisation valid throughout the EU on 9 January 2026.

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

This overview was last updated in 12-2025.