



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/351858/2022
EMA/H/W/005780

Insulatard (*human insulin*)

An overview of Insulatard and why it received a positive opinion

What is Insulatard and what is it used for?

Insulatard is a medicine for treating diabetes. It contains human insulin as its active substance.

This overview is for Insulatard intended for use outside the EU. An identical product with the same name is authorised in the European Union. For Insulatard intended for use outside EU there is an additional storage option requiring less refrigeration.

How is Insulatard used?

Insulatard is given by injection under the skin in the thigh, the abdominal wall (at the front of the waist), the gluteal region (buttocks) or the deltoid region (shoulder). The injection site should be changed for each injection. The patient's blood glucose (sugar) should be tested regularly to find the lowest effective dose.

Insulatard is a long-acting insulin. It can be given once or twice a day, with or without a fast-acting insulin (at meal times), according to the doctor's recommendation. For more information about using Insulatard, see the package leaflet or contact your healthcare provider.

How does Insulatard work?

In type 1 diabetes, the body does not make any insulin or makes too little to control the amount of glucose (sugar) in the blood, while in type 2 diabetes the main problem is that body is unable to use insulin effectively. Insulatard is a replacement insulin which is very similar to the insulin made by the pancreas.

Insulatard contains insulin mixed with another substance, protamine, in an 'isophane' form which is absorbed much more slowly during the day. This gives Insulatard a longer 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 blood glucose levels, the symptoms and complications of diabetes are reduced.



What benefits of Insulatard have been shown in studies?

Studies in adults and children have shown that treatment with Insulatard is able to lower blood sugar levels to a similar extent as other human insulins.

The results came from four studies involving 1,557 patients with type 1 diabetes and two studies involving 476 patients with type 2 diabetes. The studies compared Insulatard with other types of human insulin or insulin analogues by measuring the level of glycosylated haemoglobin (HbA1c), which is the percentage of haemoglobin in the blood that has glucose attached. HbA1c gives an indication of how well the blood glucose levels are controlled.

What are the risks associated with Insulatard?

The most common side effect with Insulatard (seen in more than 1 patient in 10) is hypoglycaemia (low blood glucose levels). For the full list of all side effects and restrictions, see the package leaflet.

Why did Insulatard receive a positive opinion?

Studies have shown that Insulatard is effective at lowering glucose levels in people with type 1 and 2 diabetes. The side effects are manageable and the European Medicines Agency concluded that the benefits of Insulatard outweigh the risks.

The Agency also looked at data on stability and concluded that the additional storage option requiring less refrigeration is acceptable.

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

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

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

Other information about Insulatard

The European Medicines Agency gave a positive opinion for Insulatard on 22 April 2022. The Agency assessed Insulatard as part of its cooperation with the World Health Organization, whereby the Agency evaluates medicines that are not intended for use in the EU but are needed to prevent or treat diseases of major public health importance around the world.

Further information on Insulatard can be found on the Agency's website: ema.europa.eu/en/opinion-medicine-use-outside-EU/human/insulatard

This overview was last updated in 05-2022.