



EUROPEAN MEDICINES AGENCY
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EPAR summary for the public

Actrapid

human insulin

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

What is Actrapid?

Actrapid is a solution for injection that contains the active substance human insulin. It is available as vials, cartridges (Penfill) or prefilled pens (NovoLet, InnoLet or FlexPen).

What is Actrapid used for?

Actrapid is used to treat diabetes.

The medicine can only be obtained with a prescription.

How is Actrapid used?

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

The usual dose is between 0.3 and 1.0 international units (IU) per kilogram body weight per day. Actrapid is given 30 minutes before a meal. Actrapid is a fast-acting insulin and may be used with intermediate or long-acting insulins. Actrapid may also be given intravenously (into a vein) but only by a doctor or a nurse.



How does Actrapid work?

Diabetes is a disease in which the body does not produce enough insulin to control the blood glucose or when the body is unable to use insulin effectively. Actrapid is a replacement insulin that is very similar to the insulin made by the pancreas.

The active substance in Actrapid, human insulin, is produced by a method known as 'recombinant technology': the insulin is made by a yeast that has received a gene (DNA), which makes it able to produce insulin. The replacement insulin acts in same way as naturally produced insulin and helps glucose enter cells from the blood. By controlling the blood glucose, the symptoms and complications of diabetes are reduced.

How has Actrapid been studied?

Actrapid has been studied in patients with type 1 diabetes, when the pancreas cannot produce insulin (two studies involving 1,954 patients), and type 2 diabetes, when the body is unable to use insulin effectively (one study involving 182 patients). The studies compared Actrapid with another replacement insulin called insulin aspart over six months 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 is controlled.

What benefit has Actrapid shown during the studies?

HbA1c levels remained fairly steady over the six months of treatment with Actrapid.

What is the risk associated with Actrapid?

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

Actrapid must not be used in people who are hypersensitive to human insulin or any of the other ingredients.

Why has Actrapid been approved?

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

Other information about Actrapid

The European Commission granted a marketing authorisation valid throughout the European Union for Actrapid on 7 October 2002.

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

This summary was last updated in 12-2012.