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Actrapid (*human insulin*)

An overview of Actrapid and why it received a positive opinion

What is Actrapid and what is it used for?

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

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

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 injection site should be changed for each injection within the same area. The patient's blood glucose (sugar) should be tested regularly to find the lowest effective dose.

Being a fast-acting insulin Actrapid is given 30 minutes before a meal 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.

For more information about using Actrapid, see the package leaflet or contact your healthcare provider.

How does Actrapid 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. Actrapid is a replacement insulin that is very similar to the insulin made by the pancreas. It acts in same way as naturally produced insulin and helps glucose enter cells from the blood. By controlling the levels of blood glucose, the symptoms and complications of diabetes are reduced.

What benefits of Actrapid have been shown in studies?

Studies in adults and children have shown that treatment with Actrapid was effective at controlling blood glucose levels. The results came from two studies involving 1,954 patients with type 1 diabetes

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and one study involving 182 patients with type 2 diabetes. 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 levels of blood glucose are controlled.

What are the risks 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 list of side effects and restrictions, see the package leaflet.

Why did Actrapid receive a positive opinion?

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

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

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

Other information about Actrapid

The European Medicines Agency gave a positive opinion for Actrapid on 22 April 2022. The Agency assessed Actrapid 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 Actrapid can be found on the Agency's website: ema.europa.eu/en/opinion-medicine-use-outside-EU/human/actrapid

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