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EPAR summary for the public

Actraphane

human insulin

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

What is Actraphane?

Actraphane is a suspension for injection that contains the active substance human insulin. It is available as vials, cartridges (Penfill) or prefilled pens (InnoLet or FlexPen). Actraphane contains both fast-acting (soluble) and long-acting (isophane) insulin:

- Actraphane 30: soluble insulin 30% and isophane insulin 70%;
- Actraphane 40: soluble insulin 40% and isophane insulin 60%;
- Actraphane 50: soluble insulin 50% and isophane insulin 50%.

What is Actraphane used for?

Actraphane is used to treat diabetes.

The medicine can only be obtained with a prescription.

How is Actraphane used?

Actraphane 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.

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The usual dose is between 0.3 and 1.0 international units (IU) per kilogram body weight per day. Actraphane is given 30 minutes before a meal. It is usually given once or twice a day when a rapid initial effect together with a more long-lasting effect is needed.

How does Actraphane 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. Actraphane is a replacement insulin which is very similar to the insulin made by the pancreas.

The active substance in Actraphane, human insulin, is produced by a method known as 'recombinant technology': the insulin is made by yeast cells into which a gene (DNA) has been introduced, which makes them able to produce insulin. Actraphane contains insulin in two forms: a soluble form, which acts quickly (within 30 minutes of injection) and an isophane form, which is absorbed much more slowly during the day. This gives Actraphane 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, the symptoms and complications of diabetes are reduced.

How has Actraphane been studied?

Actraphane has been studied in a total of 294 patients with type 1 diabetes, when the pancreas cannot produce insulin, and type 2 diabetes, when the body is unable to use insulin effectively. About one-third of the patients had type 1 diabetes and the remainder had type 2 diabetes. The study compared Actraphane 30 to a similar mix, but made up using an insulin analogue (insulin aspart). The study measured the level of glycosylated haemoglobin (HbA1c) after 12 weeks, 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 Actraphane shown during the studies?

Actraphane led to a decrease in the level of HbA1c, indicating that blood glucose levels had been controlled to a similar level to that seen with other human insulin. Actraphane was effective for both type 1 and type 2 diabetes.

What is the risk associated with Actraphane?

The most common side effect with Actraphane (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 has Actraphane been approved?

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

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

A risk management plan has been developed to ensure that Actraphane is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Actraphane, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Actraphane

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

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

This summary was last updated in 11-2013.