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EPAR summary for the public

Protaphane

human insulin

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

What is Protaphane?

Protaphane is a suspension for injection that contains the active substance human insulin. It is available as vials, cartridges (Penfill), or pre-filled pens (InnoLet or FlexPen).

What is Protaphane used for?

Protaphane is used to treat diabetes.

The medicine can only be obtained with a prescription.

How is Protaphane used?

Protaphane is given by injection under the skin, usually 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.

Protaphane is a long-acting insulin. It can be given once or twice a day, with or without a fast-acting insulin (given at meal times), according to the doctor's recommendation. The usual dose is between 0.3 and 1.0 international units (IU) per kilogram body weight per day.

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How does Protaphane 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. Protaphane is a replacement insulin which is very similar to the insulin made by the pancreas. The active substance in Protaphane, human insulin, is produced by a method known as 'recombinant technology': it is made by yeast cells into which a gene (DNA) has been introduced which makes them able to produce insulin.

Protaphane contains insulin mixed with another substance, protamine, in an 'isophane' form which is absorbed much more slowly during the day. This gives Protaphane 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 Protaphane been studied?

Protaphane has been studied in four main clinical trials, which included a total of 557 patients with type 1 diabetes, when the pancreas cannot produce insulin (two studies involving 81 patients), or type 2 diabetes, when the body is unable to use insulin effectively (two studies involving 476 patients). In most patients, Protaphane was compared with other types of human insulin or insulin analogues. The studies measured the level of fasting blood glucose or glycosylated haemoglobin (HbA1c, the haemoglobin in the blood that has glucose attached). HbA1c gives an indication of how well the blood glucose is controlled. Further studies were also carried out in 225 patients comparing injecting Protaphane using a syringe, or using a pre-filled pen (InnoLet or FlexPen).

What benefit has Protaphane shown during the studies?

Protaphane led to a decrease in the level of HbA1c, indicating that blood sugar levels had been controlled to a similar level to that seen with other human insulin. Protaphane was effective for both type 1 and type 2 diabetes, and when using a standard injection or one of the pre-filled pens.

What is the risk associated with Protaphane?

The most common side effect with Protaphane (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 Protaphane been approved?

The CHMP decided that Protaphane'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 Protaphane?

A risk management plan has been developed to ensure that Protaphane 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 Protaphane, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Protaphane

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

The full EPAR for Protaphane is available ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Protaphane, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

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