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EPAR summary for the public

Insuman

human insulin

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

What is Insuman?

Insuman is a range of insulin-containing solutions and suspensions for injection. It is supplied in vials, cartridges, or pre-filled disposable pens. The Insuman range is comprised of:

- Insuman Rapid, Insuman Infusat and Insuman Implantable, which are fast-acting insulin solutions containing soluble insulin;
- Insuman Basal, an intermediate-acting insulin suspension containing isophane insulin;
- Insuman Comb, which is available in various combinations of fast- and intermediate-acting insulins.

What is Insuman used for?

Insuman is used in patients with diabetes (type 1 and 2) who need treatment with insulin.

Insuman Rapid can also be used for the treatment of hyperglycaemic coma (coma caused by too much blood glucose [sugar]) and ketoacidosis (high levels of ketones [acids] in the blood), and to control blood glucose before, during or after an operation.

Insuman Implantable is used in adult patients with type 1 diabetes that cannot be controlled with insulin given under the skin and who often have episodes of, otherwise unexplained, hyper- or hypoglycaemia (high or low blood glucose levels).

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The medicine can only be obtained with a prescription.

How is Insuman used?

Insuman Rapid, Infusat, Basal and Comb are given by injection under the skin, generally in the abdominal wall (tummy) or the thigh, according to the doctor's recommendations. The injection site is changed for each injection. The desired blood glucose levels, the type of Insuman to be used, and the dose and timing of injections are determined by the doctor for each patient individually, and are adjusted to suit the patient's diet, physical activity and lifestyle. The patient's blood glucose should be tested regularly to find the lowest effective dose. Insuman should be given before meals. See the package leaflet for exact timings.

Insuman Rapid may also be given into a vein, but only in an intensive care unit or similar setting where the patient can be closely monitored. Insuman Infusat is specially prepared ready to be used as a continuous infusion under the skin using an external portable infusion pump.

Insuman Implantable is given only by infusion into the abdominal cavity using a pump (Medtronic MiniMed implantable pump) that is implanted under the skin of the abdomen. Insuman Implantable must not be used in any other way and can only be used in centres where staff have received adequate training in the use of the implantable pump.

Further information on the way Insuman is given can be found in the Summary of Product Characteristics (also part of the EPAR).

How does Insuman work?

Diabetes is a disease in which the body does not produce enough insulin to control the level of blood glucose (type 1 diabetes) or when the body is unable to use insulin effectively (type 2 diabetes). Insuman is a replacement insulin that is similar to the insulin made by the body.

The active substance in Insuman, human insulin, is produced by a method known as 'recombinant DNA technology': it is made by bacteria into which a gene (DNA) has been introduced that makes the bacteria able to produce insulin. Insuman contains insulin in various forms: the soluble form, which acts quickly (within 30 minutes of injection), and the isophane and crystalline-protamine forms, which are absorbed much more slowly during the day, giving them a longer duration of action.

The replacement insulin acts in the same way as naturally produced insulin and helps glucose enter cells from the blood. By controlling the level of blood glucose, the symptoms and complications of diabetes are reduced.

How has Insuman been studied?

Insuman has been studied in three trials in 780 patients with either type 1 diabetes or type 2 diabetes. In one of the studies, Insuman was given to patients with type 1 diabetes using an external insulin pump. In another study, Insuman Comb 25 was compared with semi-synthetic human insulin in patients with type 1 and type 2 diabetes. In addition, Insuman Implantable was studied in adult patients with type 1 diabetes. These patients received Insuman Implantable as a continuous infusion into the peritoneal cavity.

The main measure of effectiveness in all studies was the change in the level of glycosylated haemoglobin (HbA1c), which is the percentage of haemoglobin in the blood that has glucose attached. HbA1c levels give an indication of how well the blood glucose is controlled.

What benefit has Insuman shown during the studies?

Insuman 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 semi-synthetic human insulin. Insuman was effective for both type 1 and type 2 diabetes.

What is the risk associated with Insuman?

Insuman may cause hypoglycaemia. For the full list of all side effects reported with Insuman, see the Package Leaflet.

Insuman must not be used in people who are hypersensitive (allergic) to human insulin or any of the other ingredients. In addition, Insuman Implantable must not be used any other way than as a continuous infusion using the Medtronic MiniMed Implantable Pump. It must also not be used in patients who are hypersensitive to titanium alloy, polysulfone or silicone material used in the components of the implanted pump. No other insulins must be used with the pump and the pump must not be used in children who have not yet reached adult size. The pump must not be implanted in people who reside permanently at elevations above 2,439 metres (8000 feet).

Why has Insuman been approved?

The CHMP decided that Insuman's benefits are greater than its risks for the treatment of type 1 and type 2 diabetes. The Committee recommended that Insuman be given marketing authorisation.

Other information about Insuman

The European Commission granted a marketing authorisation valid throughout the European Union for Insuman on 21 February 1997.

The full EPAR for Insuman can be found on the Agency's website: [ema.europa.eu/Find/medicine/Human medicines/European public assessment reports](http://ema.europa.eu/Find/medicine/Human%20medicines/European%20public%20assessment%20reports). For more information about treatment with Insuman, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2013.