European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

INSULIN HUMAN WINTHROP RAPID
INSULIN HUMAN WINTHROP BASAL
INSULIN HUMAN WINTHROP COMB (15, 25, 30, 50)
INSULIN HUMAN WINTHROP INFUSAT

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Insulin Human Winthrop?
Insulin Human Winthrop is a range of insulin solutions and suspensions for injection. It is supplied in vials, cartridges, or pre-filled disposable pens (OptiSet and SoloStar).
Insulin Human Winthrop contains the active substance insulin human. The Insulin Human Winthrop range is comprised of fast-acting insulin solutions (Insulin Human Winthrop Rapid and Insulin Human Winthrop Infusat) that contain soluble insulin, an intermediate-acting insulin suspension (Insulin Human Winthrop Basal) that contains isophane insulin, and combinations of fast- and intermediate-acting in various proportions (Insulin Human Winthrop Comb):

- Insulin Human Winthrop Comb 15: 15% soluble insulin and 85% crystalline protamine insulin;
- Insulin Human Winthrop Comb 25: 25% soluble insulin and 75% crystalline protamine insulin;
- Insulin Human Winthrop Comb 30: 30% soluble insulin and 70% crystalline protamine insulin;
- Insulin Human Winthrop Comb 50: 50% soluble insulin and 50% crystalline protamine insulin.

This medicine is the same as Insuman, which is already authorised in the European Union (EU). The company that makes Insuman has agreed that its scientific data can be used for Insulin Human Winthrop.

What is Insulin Human Winthrop used for?
Insulin Human Winthrop is used in patients with diabetes who need treatment with insulin.
Insulin Human Winthrop 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.
The medicine can only be obtained with a prescription.

How is Insulin Human Winthrop used?
Insulin Human Winthrop is 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 Insulin Human Winthrop to be used, and the dose and timing of injections are determined by the doctor for each patient individually, and are

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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. Insulin Human Winthrop should be given before meals. See the Package Leaflet for exact timings.
Insulin Human Winthrop Rapid may also be given into a vein, but only in hospital where the patient can be closely monitored. Insulin Human Winthrop Infusat is specially prepared ready to be used in infusion pumps.

How does Insulin Human Winthrop work?
Diabetes is a disease in which the body does not produce enough insulin to control the level of blood glucose. Insulin Human Winthrop is a replacement insulin that is identical to the insulin made by the body.
The active substance in Insulin Human Winthrop, insulin human, is produced by a method known as 'recombinant DNA technology': it is made by a bacterium that has received a gene (DNA), which makes it able to produce insulin. Insulin Human Winthrop 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 Insulin Human Winthrop been studied?
Insulin Human Winthrop has been studied in two trials in 611 patients with either type 1 diabetes (when the body cannot produce insulin) or type 2 diabetes (when the body is unable to use insulin effectively). In one of the studies, Insulin Human Winthrop was used in an insulin pump. In the other study, Insulin Human Winthrop Comb 25 was compared with semi-synthetic human insulin. The studies measured the 'fasting' blood glucose levels (measured when the patient had not eaten for at least eight hours), or the levels of a substance in the blood called glycosylated haemoglobin (HbA1c), which gives an indication of how well the blood glucose is controlled. The studies also looked at the number of patients who developed hypoglycaemia (low blood glucose levels).

What benefit has Insulin Human Winthrop shown during the studies?
Insulin Human Winthrop 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. Insulin Human Winthrop was effective for both type 1 and type 2 diabetes.

What is the risk associated with Insulin Human Winthrop?
Insulin Human Winthrop can cause hypoglycaemia. For the full list of all side effects reported with Insulin Human Winthrop, see the Package Leaflet.
Insulin Human Winthrop should not be used in people who may be hypersensitive (allergic) to insulin human or any of the other ingredients. Insulin Human Winthrop doses might need to be adjusted when it is given with other medicines that may have an effect on blood glucose levels. The full list of these medicines is available in the Package Leaflet.

Why has Insulin Human Winthrop been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Insulin Human Winthrop's benefits are greater than its risks for the treatment of diabetes mellitus. The Committee recommended that Insulin Human Winthrop be given marketing authorisation.

Other information about Insulin Human Winthrop:
The European Commission granted a marketing authorisation valid throughout the EU for Insulin Human Winthrop to Sanofi-Aventis Deutschland GmbH on 17 January 2007.

The full EPAR for Insulin Human Winthrop is available here.

This summary was last updated in 12-2008.