European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

VELOSULIN

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 Velosulin?
Velosulin is a solution for injection or infusion (drip). It contains the active substance insulin human (rDNA).

What is Velosulin used for?
Velosulin is used to treat patients with diabetes.
The medicine can only be obtained with a prescription.

How is Velosulin used?
Velosulin is intended for continuous subcutaneous infusion (under the skin) using an insulin infusion pump. Velosulin may also be injected into a vein or given subcutaneously by injection. Velosulin is a fast-acting insulin and may be used with longer-acting insulin products.
The patient's blood glucose (sugar) should be tested regularly to find the lowest effective dose. Velosulin should be given before meals. See the Package Leaflet for exact timings.

How does Velosulin work?
Diabetes is a disease in which the body does not produce enough insulin to control the blood glucose. Velosulin is a replacement insulin that is identical to the insulin made by the pancreas. The active substance in Velosulin, insulin human (rDNA), is produced by a method known as 'recombinant DNA technology': the insulin is made by a yeast that has received a gene (DNA), which makes it able to produce insulin. The replacement insulin acts in same way as naturally produced insulin and helps glucose to enter cells from the blood. By controlling the blood glucose, the symptoms and complications of diabetes are reduced. The solution of insulin in Velosulin is specially prepared to make it stable for the duration of administration in an infusion pump.

How has Velosulin been studied?
The studies used to support Velosulin are those that have been used to support Actrapid, another insulin approved in the European Union (EU). The studies measured the level of fasting blood sugar or a substance in the blood called glycosylated haemoglobin (HbA1c), which gives an indication of how well the blood glucose is controlled. Velosulin has also been studied used in an insulin pump.

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What benefit has Velosulin shown during the studies?
Velosulin 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 the other human insulin. Velosulin was effective for both type 1 and type 2 diabetes.

What is the risk associated with Velosulin?
As with all insulins, Velosulin may cause hypoglycaemia (low blood glucose). For the full list of all side effects reported with Velosulin, see the Package Leaflet.
Velosulin should not be used in people who may be hypersensitive (allergic) to insulin human (rDNA) or to any of the other ingredients. Velosulin doses might also need to be adjusted when given with a number of other medicines which may have an effect on blood glucose. The full list is available in the Package Leaflet.

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

Other information about Velosulin:
The European Commission granted a marketing authorisation valid throughout the EU for Velosulin to Novo Nordisk A/S on 7 October 2002. The marketing authorisation was renewed on 7 October 2007.

The full EPAR for Velosulin is available here.

This summary was last updated in 10-2007.