EMA/632418/2016
EMEA/H/C/000258

EPAR summary for the public

NovoRapid

insulin aspart

This is a summary of the European public assessment report (EPAR) for NovoRapid. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use NovoRapid.

For practical information about using NovoRapid, patients should read the package leaflet or contact their doctor or pharmacist.

What is NovoRapid and what is it used for?

NovoRapid is used to treat adults, adolescents and children over one year old who have diabetes. It contains the active substance insulin aspart, a rapid-acting insulin.

How is NovoRapid used?

NovoRapid is a solution for injection available in vials, cartridges (PenFill and PumpCart) and pre-filled pens (FlexPen, FlexTouch and InnoLet) and can only be obtained with a prescription. It is given by injection under the skin in the abdominal (belly) wall, the thigh, the upper arm, the shoulder or the buttock. The injection site should be changed for each injection. Patients can inject themselves under the skin with NovoRapid if they have been trained appropriately.

NovoRapid is usually given immediately before a meal, although it may be given after a meal if necessary. NovoRapid is normally used in combination with an intermediate- or long-acting insulin given at least once a day. The patient's blood glucose (sugar) should be tested regularly to find the lowest effective dose.

The usual dose is between 0.5 and 1.0 units per kilogram body weight per day. When it is used with meals, 50 to 70% of the insulin requirement may be provided by NovoRapid and the remainder by an intermediate or long-acting insulin. NovoRapid can be used in pregnant women.

NovoRapid can also be used in a pump system for continuous insulin infusion under the skin or alternatively, it can be given into a vein but only by a doctor or a nurse.

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How does NovoRapid work?

Diabetes is a disease in which the body does not produce enough insulin to control the level of blood glucose. NovoRapid is a replacement insulin that is very similar to the insulin made by the body but is absorbed faster by the body. This allows it to start acting faster than human insulin. The replacement insulin works 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.

What benefits of NovoRapid have been shown in studies?

NovoRapid gave almost identical results to human insulin in two studies involving 1,954 patients with type 1 diabetes (when the pancreas cannot produce insulin) and in one study involving 182 patients with type 2 diabetes (when the body is unable to use insulin effectively). The studies compared NovoRapid with human insulin by measuring the level of a substance in the blood called glycosylated haemoglobin (HbA1c), which gives an indication of how well the blood glucose is controlled. NovoRapid reduced HbA1c levels by 0.12% and by 0.15% more than human insulin did after six months. NovoRapid has also given comparable results when studied in children from one year of age. The safety has been found to be the same as human insulin when compared in two studies involving 349 pregnancies in women with type 1 or gestational diabetes (diabetes caused by pregnancy).

What are the risks associated with NovoRapid?

The most common side effect with NovoRapid (seen in between 1 and 10 patients in 100) is hypoglycaemia (low blood glucose levels). For the full list of all side effects and restrictions with NovoRapid, see the package leaflet.

Why is NovoRapid approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that NovoRapid'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 NovoRapid?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of NovoRapid have been included in the summary of product characteristics and the package leaflet.

Other information about NovoRapid

The European Commission granted a marketing authorisation valid throughout the European Union for NovoRapid on 7 September 1999.

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

This summary was last updated in 09-2016.