European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

MONOTARD

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 Monotard?

Monotard is an insulin suspension for injection. Monotard is supplied as 40 or 100 IU strengths in vials. Monotard contains the active ingredient insulin human (rDNA).

What is Monotard used for?

Monotard is used in patients with diabetes mellitus. Monotard can be used in type 1 diabetes, when the pancreas cannot produce insulin, and in type 2 diabetes, when the body is not able to use insulin effectively.
The medicine can only be obtained with a prescription.

How is Monotard used?

Monotard is given subcutaneously (under the skin) by injection, usually in the thigh. If convenient it may also be given in the abdominal wall (tummy), the buttocks or the deltoid region (shoulder). The patient's blood sugar should be tested regularly to find the lowest effective dose. In type 1 diabetes, the dosage varies between 0.5 and 1.0 IU/kg (0.7 and 1.0 IU/kg in children before puberty), in type 2 diabetes the dosage is 0.3 to 0.6 IU/kg. Monotard is a long-acting insulin, it can be given as a once daily or twice daily injection, with or without a fast-acting insulin (at meal times), according to the doctor’s recommendation.

How does Monotard work?

Diabetes is a disease in which the body does not produce enough insulin to control the blood sugar. Monotard is a replacement insulin which identical to the insulin made by the pancreas .The active ingredient of Monotard, insulin human (rDNA), is produced by a method known as ‘recombinant technology’. The insulin is made by a yeast that has received a gene (DNA), which makes it able to produce insulin. Monotard contains insulin mixed with another substance, zinc, in particles from which the insulin is absorbed much more slowly during the day; and this gives Monotard 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 sugar, the symptoms and complications of diabetes are reduced.

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How has Monotard been studied?
Monotard has been studied in both type 1 and type 2 diabetes, and it has been compared to other types of insulin (porcine, human). The studies measured the level of fasting blood sugar or a substance (glycosylated haemoglobin, HbA1c), which gives an indication of how well the blood sugar is controlled.

What benefit has Monotard shown during the studies?
Monotard 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. Monotard was effective for both Type 1 and Type 2 diabetes.

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

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

Other information about Monotard:
The European Commission granted a marketing authorisation valid throughout the European Union, for Monotard to Novo Nordisk A/S in on 7 October 2002.

The full EPAR for Monotard is available here.

This summary was last updated in 1-2006