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EPAR summary for the public

Nonafact

human coagulation factor IX

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

What is Nonafact?

Nonafact is a powder and solvent that are mixed together to form a solution for infusion (drip) into a vein. Nonafact contains the active substance human coagulation factor IX, which helps blood to clot.

What is Nonafact used for?

Nonafact is used for the treatment and prevention of bleeding in patients with haemophilia B (an inherited bleeding disorder caused by lack of factor IX). Nonafact can be used in adults and children over the age of 6. Nonafact is intended for either short-term or long-term use.

The medicine can only be obtained with a prescription.

How is Nonafact used?

Treatment should be started under the supervision of a doctor with experience in treating haemophilia. Nonafact is given by infusion into a vein at a rate of no more than 2 ml per minute. The doctor will calculate a suitable dose, depending on whether Nonafact is used to treat haemorrhage (bleeding) or to prevent bleeding during surgery. The dose is also adjusted depending on the severity of the haemorrhage or the type of surgery. It is generally given once a day, except in life-threatening situations. Patients may sometimes be able to give the medicine themselves after suitable training. The full detail on how to calculate the doses is included in the package leaflet.

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How does Nonafact work?

Nonafact contains human coagulation factor IX, a protein extracted and purified from human plasma (the liquid part of the blood). In the body, factor IX is one of the substances (factors) needed for blood coagulation (clotting). Patients with haemophilia B lack factor IX, and this causes bleeding problems, such as bleeding in the joints, muscle or internal organs. Nonafact is used to replace the missing factor IX; it corrects the factor IX deficiency and gives temporary control of the bleeding disorder.

How has Nonafact been studied?

Nonafact has been studied in two clinical studies, including 26 patients who received Nonafact as a prevention treatment (for example before extensive exercise), and 8 patients who received Nonafact during 11 surgical interventions. Most patients had severe haemophilia B. The studies assessed the number of major or life-threatening bleeding episodes that occurred during treatment, or during and after surgery.

What benefit has Nonafact shown during the studies?

Nonafact was rated as “good” or “excellent” in its ability to prevent bleeding in patients with haemophilia B.

What is the risk associated with Nonafact?

Haemophilia B patients may develop antibodies (inhibitors) to factor IX. If this happens Nonafact may not work effectively. Hypersensitivity (allergic reactions) has been sometimes seen in patients treated with factor IX-containing products. For the full list of all the side effects reported with Nonafact, see the package leaflet.

Nonafact must not be used in people who are hypersensitive (allergic) to human coagulation factor IX or to any of the other ingredients, or to mouse proteins.

Why has Nonafact been approved?

The CHMP decided that Nonafact’s benefits are greater than its risks for the treatment and prevention of bleeding in patients with haemophilia B. They recommended that Nonafact be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Nonafact?

A risk management plan has been developed to ensure that Nonafact is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Nonafact, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Nonafact

The European Commission granted a marketing authorisation valid throughout the European Union, for Nonafact on 3 July 2001.

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

This summary was last updated in 01-2016.