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EPAR summary for the public

ReFacto AF

moroctocog alfa

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

What is ReFacto AF?

ReFacto AF is a powder and solvent used to make up a solution for injection. ReFacto AF contains the active substance moroctocog alfa. It is available as vials or pre-filled syringes.

What is ReFacto AF used for?

ReFacto AF is used for the treatment and prevention of bleeding in patients with haemophilia A (an inherited bleeding disorder). ReFacto AF can be used in patients of all ages, including newborns.

The medicine can only be obtained with a prescription.

How is ReFacto AF used?

ReFacto AF should be started under the supervision of a doctor who has experience in the treatment of haemophilia A.

ReFacto AF is given by injection into a vein over several minutes. The dose and the frequency of treatment depend on whether ReFacto AF is used to treat or prevent bleeding, the seriousness of the condition, the extent and location of the bleeding or the type of surgery, and the patient's bodyweight. Full details on how to calculate the dose are included in the summary of product characteristics (also part of the EPAR).

Patients or their carers can give injections of ReFacto AF, provided that they have been trained appropriately.



How does ReFacto AF work?

Patients with haemophilia A lack factor VIII, a protein needed for normal clotting of the blood, and as a result, they bleed readily and may have problems, such as bleeding in the joints, muscles and internal organs. The active substance in ReFacto AF, moroctocog alfa, works in the body in the same way as human factor VIII. It replaces the missing factor VIII, thereby helping the blood to clot and giving temporary control of bleeding.

The human coagulation factor VIII in ReFacto AF is not extracted from human blood but is produced by a method known as 'recombinant DNA technology': it is made by a cell that has received a gene (DNA), which makes it able to produce human coagulation factor VIII.

How has ReFacto AF been studied?

ReFacto AF was first authorised as ReFacto in April 1999, for use in previously treated and untreated patients with haemophilia A, based on the results of three main studies. In February 2009, a number of changes to the way ReFacto is made were introduced. These included removal of the use of a protein called albumin, which is produced from human blood, from the manufacturing process. The name of the medicine was also changed from ReFacto to ReFacto AF.

Following these changes, the company carried out a study to show that ReFacto and ReFacto AF were treated by the body in the same way. It also carried out two main studies looking at the effectiveness of ReFacto AF: the first looked at the prevention and treatment of bleeding episodes in 94 previously treated patients and the second looked at the prevention of bleeding in 22 patients having surgery.

What benefit has ReFacto AF shown during the studies?

The studies showed that ReFacto AF was as safe and effective as ReFacto in preventing and treating bleeding episodes in patients with haemophilia A.

What is the risk associated with ReFacto AF?

The most common side effects with ReFacto AF (seen in more than 1 patient in 10) are headache, cough, pain in the joints and fever. Patients may also develop antibodies against factor VIII medicines such as ReFacto AF. These are known as inhibitors as they can prevent the medicine from working effectively, which may result in a loss of bleeding control. Uncommonly, patients may also develop allergic reactions. For the full list of all side effects reported with ReFacto AF, see the package leaflet.

ReFacto AF must not be used in people who are hypersensitive (allergic) to human coagulation factor VIII, to any of the other ingredients or to hamster proteins.

Why has ReFacto AF been approved?

The CHMP noted that ReFacto AF was comparable to ReFacto, the original form of the medicine. Therefore, the Committee decided that the benefits of ReFacto AF 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 ReFacto AF?

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

Other information about ReFacto AF

The European Commission granted a marketing authorisation valid throughout the European Union for ReFacto AF on 13 April 1999.

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

This summary was last updated in 07-2016.