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EPAR summary for the public

Kogenate Bayer

octocog alfa

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

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

What is Kogenate Bayer and what is it used for?

Kogenate Bayer is a medicine used for the treatment and prevention of bleeding in patients of all ages with haemophilia A (an inherited bleeding disorder caused by lack of factor VIII). It contains the active substance octocog alfa (human coagulation factor VIII).

How is Kogenate Bayer used?

Kogenate Bayer can only be obtained with a prescription and treatment should be started by a doctor experienced in the treatment of haemophilia.

Kogenate Bayer is available as a powder and solvent that are mixed together to make a solution for injection or infusion (drip) into a vein. The dose and duration of treatment depend on whether it is used to treat or prevent bleeding or during surgery, as well as on the patient's factor VIII levels, the seriousness of the haemophilia, the extent and location of the bleeding and the patient's condition and bodyweight. The dose may need to be adjusted if Kogenate Bayer is to be given continuously as an infusion into a vein. Kogenate Bayer is intended for either short-term or long-term use.

Patients or their carers may be able to administer Kogenate Bayer themselves at home once they have been trained appropriately. For full details, see the package leaflet.

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How does Kogenate Bayer work?

The active substance in Kogenate Bayer, octocog alfa (human coagulation factor VIII), is a substance that helps the blood to clot. Patients with haemophilia A lack factor VIII, and this causes blood clotting problems, such as bleeding in the joints, muscles and internal organs. Kogenate Bayer is used to correct the factor VIII deficiency by replacing the missing factor VIII, giving temporary control of the bleeding disorder.

Octocog alfa is made by a method known as 'recombinant DNA technology': it is made by cells into which a gene (DNA) has been introduced that makes them able to produce it.

What benefits of Kogenate Bayer have been shown in studies?

Kogenate Bayer is similar to another medicine that was previously authorised in the EU called Kogenate, but it is prepared differently so that there are no human-derived proteins in the medicine. Because of this, Kogenate Bayer has been compared with Kogenate to show that the two medicines are equivalent.

Kogenate Bayer given as an injection into a vein has been studied in 66 patients who had previously been treated with recombinant human coagulation factor VIII and 61 children who had not. The main measure of effectiveness in the studies was the number of treatments required to stop each new bleed. In the previously treated patients, overall, 95% of bleeds responded to one or two injections of Kogenate Bayer into a vein. In the previously untreated patients, about 90% of bleeding episodes responded to treatment with one or two injections into a vein.

Kogenate Bayer as a continuous infusion has also been studied in 15 patients with haemophilia A undergoing major surgery. The main measure of effectiveness was the doctor's assessment of how well bleeding was stopped. Stopping bleeding was assessed as 'excellent' in all 15 patients.

Some patients may develop factor VIII inhibitors, which are antibodies (proteins) that the body's immune system produces against factor VIII and which can cause the medicine to stop working resulting in a loss of bleeding control. Kogenate Bayer given at high dose has been studied to see whether it is effective in clearing antibodies against factor VIII from the blood (a process known as immune tolerance induction) so that treatment with factor VIII remains effective. The data provided on immune tolerance induction in patients with inhibitors showed that some patients benefit from the high dosage and the inhibitor could be eliminated, nevertheless the data were not considered sufficient to specifically approve the medicine for this use.

What are the risks associated with Kogenate Bayer?

Hypersensitivity (allergic) reactions have been reported with factor VIII medicines and may in some cases become severe. Skin- associated hypersensitivity reactions (itching, hives and rash) may occur commonly (in between 1 and 10 patients in 100) but a severe allergic reaction is rare (between 1 and 10 in 10,000 patients).

There is a risk with factor VIII medicines that some patients will develop inhibitors (antibodies) against factor VIII, causing the medicine to stop working and resulting in a loss of bleeding control. In such cases, a specialised haemophilia centre should be contacted.

For the full list of all side effects reported with Kogenate Bayer, see the package leaflet. Kogenate Bayer must not be used in people who are known to be hypersensitive (allergic) to human coagulation factor VIII, to mouse or hamster protein, or to any of the other ingredients.

Why is Kogenate Bayer approved?

The Agency decided that Kogenate Bayer's benefits are greater than its risks and recommended that it be given marketing authorisation. The Agency concluded that Kogenate Bayer has been shown to be effective at treating and preventing bleeding in patients with haemophilia A and has an acceptable safety profile.

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

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

Other information about Kogenate Bayer

The European Commission granted a marketing authorisation valid throughout the EU for Kogenate Bayer on 4 August 2000.

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

This summary was last updated in 10-2017.