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EPAR summary for the public

Advate

octocog alfa

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

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

What is Advate and what is it used for?

Advate 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 Advate used?

Advate can only be obtained with a prescription and treatment should be started by a doctor experienced in the treatment of haemophilia and with resuscitation equipment available in case of severe allergic reaction (anaphylaxis).

Advate is available as a powder and solvent that are mixed together to make a solution for injection into a vein. The dose and duration of treatment depend on whether Advate 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. Advate is intended for either short-term or long-term use.

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

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How does Advate work?

The active substance in Advate, 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 or internal organs. Advate 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 Advate have been shown in studies?

Advate is similar to another medicine approved in the EU called Recombinate, but it is prepared differently so that there are no human- or animal-derived proteins in the medicine. Because of this Advate has been compared with Recombinate to show that the two medicines are equivalent in one main study including 111 patients with haemophilia A.

The study went on to look at the number of bleeding episodes and rated Advate's effectiveness in stopping bleeding on a scale from 'none' to 'excellent' in 107 patients, all of whom received Advate. The effectiveness of Advate was rated as 'excellent' or 'good' in 86% of 510 new bleeding episodes. In addition, 81% of these bleeding episodes required only a single treatment with Advate.

Three additional studies looked at the use of the medicine in the prevention of bleeding and in surgery in patients with severe or moderately severe haemophilia A, including one study in 53 children under the age of 6 years. The additional studies confirmed Advate's effectiveness, including in children under 6 years of age.

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. Advate 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 were not considered sufficient to specifically approve the medicine for this use.

What are the risks associated with Advate?

Common side effects with Advate (affecting between 1 and 10 patients in 100) are headache and pyrexia (fever).

Hypersensitivity (allergic) reactions have been reported and may in some cases become severe.

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 Advate, see the package leaflet. Advate must not be used in people who are hypersensitive (allergic) to human coagulation factor VIII, to mouse or hamster protein, or to any of the other ingredients.

Why is Advate approved?

The Agency decided that Advate's benefits are greater than its risks and recommended that it be given marketing authorisation. The Agency concluded that Advate 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 Advate?

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

Other information about Advate

The European Commission granted a marketing authorisation valid throughout the EU for Advate on 2 March 2004.

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

This summary was last updated in 10-2017.