EMA/753310/2016
EMEA/H/C/004075

EPAR summary for the public

Afstyla

lonoctocog alfa

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

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

What is Afstyla and what is it used for?

Afstyla is a medicine used for the treatment and prevention of bleeding in patients with haemophilia A (an inherited bleeding disorder caused by lack of a clotting protein called factor VIII). It contains the active substance lonoctocog alfa.

How is Afstyla used?

Afstyla is available as a powder and solvent used to make a solution for injection. The injection is given into a vein over several minutes. The dose and frequency of the injections depend on whether Afstyla is used to treat or prevent bleeding, the severity of the patient's factor VIII deficiency, the extent and location of the bleeding and the patient's condition and bodyweight.

Afstyla can only be obtained with a prescription and treatment should be under the supervision of a doctor who has experience in the treatment of haemophilia. For further information, see the package leaflet.

How does Afstyla work?

Patients with haemophilia A lack factor VIII, a protein needed for normal clotting of the blood, and as a result, they bleed readily.

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The active substance in Afstyla, lonoctocog alfa, is a shorter version of human factor VIII that 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.

What benefits of Afstyla have been shown in studies?

Afstyla has been shown to be effective at preventing and treating bleeding episodes in two main studies in patients with severe haemophilia A who were previously treated with other factor VIII products.

The first study involved 173 patients aged 12 years and above. A total of 848 bleeding episodes were recorded during the study, 94% of which resolved with one or two injections of Afstyla. Afstyla was rated as 'excellent' or 'good' at treating 92% of the bleeding episodes. In the 16 surgical procedures that occurred during the study, Afstyla was rated as 'excellent' or 'good' in preventing bleeding episodes when used two to three times a week. Among those patients who received Afstyla to prevent bleeding, an average of 1.14 bleeding episodes per year was recorded for each patient which was lower than the 19.64 episodes per year in patients not receiving Afstyla for prevention.

The second study involved 83 patients below 12 years of age. Afstyla was rated as 'excellent' or 'good' at treating 96% of the 347 bleeding episodes recorded during the study; 96% of bleeding episodes resolved with one or two injections of Afstyla. Among those patients who received Afstyla to prevent bleeding, the average number of bleeding episodes per year was 2.30 for patients receiving Afstyla three times a week, and 4.37 for those receiving Afstyla twice a week.

What are the risks associated with Afstyla?

Hypersensitivity (allergic) reactions are common with Afstyla, affecting up to 1 in 10 people. They may include: angioedema (swelling of tissues under the skin), burning and stinging at the injection site, chills, flushing, itchy rash over the whole body, headache, hives, hypotension (low blood pressure), lethargy, nausea (feeling sick), restlessness, tachycardia (rapid heartbeat), tightness of the chest, tingling, vomiting and wheezing. In some cases these reactions can become severe.

There is also 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.

Afstyla must not be used in patients with known allergy to hamster proteins.

For the full list of all side effects and restrictions, see the package leaflet.

Why is Afstyla approved?

Afstyla has been shown to be effective in both preventing and treating bleeding episodes. Regarding safety, the reported side effects are in line with those expected for a factor VIII product, although hypersensitivity reactions occurred more frequently with Afstyla. Further safety data should be provided by ongoing studies.

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Afstyla's benefits are greater than its risks and recommended that it be approved for use in the EU.

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

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

Other information about Afstyla

The European Commission granted a marketing authorisation valid throughout the European Union for Afstyla on 4 January 2017.

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

This summary was last updated in 01-2017.