



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/697822/2018
EMA/H/C/003964

Elocta (*efmoroctocog alfa*)

An overview of Elocta and why it is authorised in the EU

What is Elocta and what is it used for?

Elocta is a medicine used to treat and prevent bleeding in patients with haemophilia A (an inherited bleeding disorder caused by lack of factor VIII). It contains the active substance efmorococog alfa.

How is Elocta used?

Elocta 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 Elocta 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.

Elocta can only be obtained with a prescription and treatment should be started under the supervision of a doctor who has experience in the treatment of haemophilia. For more information about using Elocta, see the package leaflet or contact your doctor or pharmacist.

How does Elocta work?

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

What benefits of Elocta have been shown in studies?

Two main studies of Elocta showed that the medicine is effective at both preventing and treating bleeding episodes.

In a study of 165 adult patients with haemophilia A, patients who were given Elocta as a tailored preventive treatment had around 3 bleeding episodes a year, which compares with 37 episodes a year in patients not given preventive treatment. In addition, when bleeding did occur, Elocta treatment was rated as 'excellent' or 'good' in more than 78% of cases, with 87% of bleeding episodes resolving with only one injection.



In a study in 69 children, Elocta was similarly effective: 2 bleeding episodes occurred per year on average and 81% of bleeding episodes resolved with only one injection.

What are the risks associated with Elocta?

Hypersensitivity (allergic) reactions are seen rarely with Elocta and these include: swelling of the face, rash, hives, tightness of the chest and difficulty breathing, burning and stinging at the injection site, chills, flushing, itching over the whole body, headache, low blood pressure, lethargy, nausea, restlessness, and a fast heartbeat. 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.

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

Why is Elocta authorised in the EU?

Studies show that Elocta is effective at preventing and treating bleeding episodes in patients with haemophilia A and its safety is in line with what is expected for medicines of its kind. The European Medicines Agency therefore decided that Elocta's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

As for all medicines, data on the use of Elocta are continuously monitored. Side effects reported with Elocta are carefully evaluated and any necessary action taken to protect patients.

Other information about Elocta

Elocta received a marketing authorisation valid throughout the EU on 19 November 2015.

Further information on Elocta can be found on the Agency's website:
ema.europa.eu/medicines/human/EPAR/Elocta.

This summary was last updated in 10-2018.