EMA/416057/2018
EMEA/H/C/002719

NovoEight (*turoctocog alfa*)

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

What is NovoEight and what is it used for?

NovoEight is a medicine used to treat and prevent bleeding in patients with haemophilia A (an inherited bleeding disorder caused by lack of factor VIII). NovoEight is intended for either short-term or long-term use.

The medicine contains the active substance turoctocog alfa.

How is NovoEight used?

NovoEight 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.

NovoEight is available as a powder and solvent that are mixed together to make a solution for injection into a vein. The dose and frequency of treatment depend on whether it is used to treat or prevent bleeding, as well as the seriousness of the haemophilia, the extent and location of the bleeding and the patient's age and condition.

Patients or their carers may be able to inject NovoEight themselves at home once they have been trained appropriately.

For more information about using NovoEight, see the package leaflet or contact your doctor or pharmacist.

How does NovoEight work?

Patients with haemophilia A lack factor VIII, which causes blood clotting problems, such as bleeding in the joints, muscles or internal organs. The active substance in NovoEight, turoctocog alfa, works in the body in the same way as human factor VIII and helps the blood to clot. NovoEight is used to correct the factor VIII deficiency by replacing the missing factor VIII, thereby giving temporary control of the bleeding disorder.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom

Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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

What benefits of NovoEight have been shown in studies?

NovoEight was effective at preventing and treating bleeding episodes in two main studies involving a total of 213 patients with haemophilia A. Neither study compared NovoEight with any other medicines.

In the first study involving 150 patients aged 12 years and above, adolescents who used NovoEight to prevent bleeding had an average of 5.55 bleeding episodes per year and adults had an average of 6.68 bleeding episodes per year. When used for the treatment of spontaneous bleeding, NovoEight was rated as 'excellent' or 'good' at treating 403 of 499 of the bleeding episodes. In addition, 89.4% of the bleeding episodes resolved after 1 to 2 doses of NovoEight.

In the second study involving 63 children less than 12 years of age, children treated with NovoEight had an average of 5.33 bleedings per year. NovoEight was rated as 'excellent' or 'good' at treating 116 of the 126 bleeding episodes. In addition, 95.2% of the bleeding episodes resolved after 1 to 2 doses of NovoEight.

What are the risks associated with NovoEight?

Hypersensitivity (allergic) reactions have been reported rarely with NovoEight and may in some cases progress to severe allergic reactions. 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. In such cases, a specialised haemophilia centre should be contacted.

For the full list of all side effects reported with NovoEight, see the package leaflet.

NovoEight must not be used in patients who are allergic to hamster protein. For the full list of restrictions, see the package leaflet.

Why is NovoEight authorised?

The European Medicines Agency decided that NovoEight's benefits are greater than its risks and it can be authorised for use in the EU. The Agency concluded that NovoEight has been shown to be effective at treating and preventing bleeding episodes, with effects similar to other factor VIII products. The safety profile of NovoEight was also considered similar to other factor VIII products.

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

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

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

Other information about NovoEight

NovoEight received a marketing authorisation valid throughout the European Union on 13 November 2013.

Further information on NovoEight can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

This overview was last updated in 07-2018.