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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.

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 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. For continuing treatment, the doctor may adjust the dose and frequency of injection according to the blood levels of factor VIII.

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

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 prevents blood from clotting and can cause problems such as bleeding in the joints, muscles or internal organs. The active substance in NovoEight, turoctocog alfa, works in the same way as natural 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.

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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 bleeding episodes 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 can occur rarely with NovoEight and may in some cases progress to severe allergic reactions. Some patients may develop factor VIII inhibitors, which can cause the medicine to stop working, resulting in a loss of bleeding control. These inhibitors are antibodies that the immune system (the body's natural defences) produces against factor VIII.

NovoEight must not be used in patients who are allergic to hamster protein.

For the full list of side effects and 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 is effective for 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/en/medicines/human/EPAR/novoeight.

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