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Cevenfacta (*eptacog beta [activated]*)

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

What is Cevenfacta and what is it used for?

Cevenfacta is a medicine used to treat bleeding episodes and to prevent bleeding in patients undergoing surgery. It is used in adults and adolescents aged 12 years or older with inherited haemophilia who have developed or are expected to develop inhibitors (antibodies) against coagulation factors VIII or IX (proteins involved in blood clotting), or who are unlikely to respond to treatment with these coagulation factors.

Cevenfacta contains the active substance eptacog beta (activated).

How is Cevenfacta used?

Cevenfacta can only be obtained with a prescription and treatment must be started and supervised by a doctor who is experienced in the treatment of haemophilia or bleeding disorders.

The medicine is given as an injection into a vein.

For the treatment of bleeding episodes, an initial dose should be given as soon as possible after the first sign of a bleed. For mild to moderate bleeds, patients can be given a starting dose of 225 microgram per kilogram body weight and, if the bleeding is not controlled after 9 hours, doses of 75 microgram per kilogram should be given every 3 hours until the bleed is controlled. Patients can also start on 75 micrograms per kilogram, repeated every 3 hours until control of the bleed. For severe bleeds, patients should be given 225 micrograms per kilogram and, if the bleeding is not controlled within 6 hours after the first dose, doses of 75 microgram per kilogram should be given every 2 hours until the bleed is controlled.
For the prevention of bleeding during surgical or other medical procedures, Cevenfacta is given before and during the procedure, and in some cases for several days after, with the dose depending on the type of surgery.

Patients or caregivers may be able to give Cevenfacta themselves after suitable training, but treatment at home should not exceed 24 hours without consulting the treating doctor.

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

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How does Cevenfacta work?

The active substance in Cevenfacta, eptacog beta, is produced from rabbit milk by recombinant DNA technology. It is almost identical to a human protein called coagulation factor VII and works in the same way. In the body, factor VII is involved in blood clotting by activating another clotting factor (called factor X), which then starts a series of steps to form a blood clot at the site of bleeding.

By activating factor X, Cevenfacta can control the bleed in people with haemophilia A or B who do not have, do not have enough, or have developed inhibitors against clotting factors VIII or IX.

What benefits of Cevenfacta have been shown in studies?

The benefits of Cevenfacta were evaluated in a main study in adults and adolescents (over 12 years of age) with haemophilia A or B with inhibitors. In this study, Cevenfacta was not compared with another treatment.

Twenty-seven patients were given Cevenfacta after bleeding episodes, and in 81.0% (204 out of 252) of the episodes treated with a lower dose (75 microgram per kg of patient body weight) and 90.3% (195 out of 216) of the episodes treated with a higher dose (225 microgram per kg of patient body weight) the symptoms had largely been reduced or had completely disappeared 12 hours after the first injection.

In another study which investigated Cevenfacta in the prevention of uncontrolled bleeding during and after surgical procedures, 12 patients with haemophilia A or B received the medicine before, during and after surgery. Two days after surgery, control of postoperative blood loss was considered good or excellent in 81.8% (9 out of 12) of surgeries.

What are the risks associated with Cevenfacta?

The most common side effects with Cevenfacta (which may affect more than 1 in 100 people) are injection site discomfort and haematoma (a collection of blood under the skin) as well as injection-related reactions, an increase in body temperature, dizziness and headache.

Cevenfacta must not be used in people who are hypersensitive (allergic) to eptacog beta, to rabbits or rabbit proteins, or to any of the other ingredients.

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

Why is Cevenfacta authorised in the EU?

Available treatment options in patients with haemophilia with inhibitors are very limited. Treatment with Cevenfacta was effective in controlling bleeding episodes in patients aged 12 and older, and side effects were mild. The European Medicines Agency therefore decided that the benefits of Cevenfacta are greater than its risks and that it can be authorised for use in the EU.

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

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

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

Other information about Cevenfacta

Cevenfacta received a marketing authorisation valid throughout the EU on 15 July 2022.

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

This overview was last updated in 07-2022.