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NovoThirteen (*catridecacog*)

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

What is NovoThirteen and what is it used for?

NovoThirteen is a medicine that prevents excessive bleeding in patients with an inherited blood clotting disorder called 'congenital factor XIII A-subunit deficiency'. It is used to prevent bleeding and to treat any episodes of bleeding that occur during preventative treatment.

NovoThirteen contains the active substance catridecacog.

How is NovoThirteen used?

NovoThirteen can only be obtained with a prescription and treatment with the medicine should be started under the supervision of a doctor experienced in treating rare bleeding disorders.

NovoThirteen is given by injection into a vein. For prevention, it is given once a month as long-term treatment. The dose is based on the patient's weight and, sometimes, factor XIII levels in the blood. For treating a bleeding episode during preventative treatment, the patient is given a single dose based on the patient's weight or, to prevent bleeding from minor surgery, on factor XIII levels.

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

How does NovoThirteen work?

Factor XIII is a protein involved in the blood clotting process. A specific component of factor XIII called the A-subunit strengthens the clot and prevents further bleeding. Patients with congenital factor XIII A-subunit deficiency do not have enough of the A-subunit, or it does not work correctly, which makes them prone to excessive bleeding. The active substance in NovoThirteen, catridecacog, has the same chemical structure as the human factor XIII A-subunit. By providing the factor XIII A-subunit, NovoThirteen helps to prevent bleeding in these patients.

What benefits of NovoThirteen have been shown in studies?

NovoThirteen was investigated in a main study involving 41 patients above 6 years of age with congenital factor XIII A-subunit deficiency who had been treated in the past with medicines containing factor XIII. On average, each patient treated preventatively with NovoThirteen had about 0.15 bleeding episodes requiring factor XIII treatment per year. This compared with around 2.9 episodes

per year for patients treated with another factor XIII medicine, which was given when necessary to control bleeding.

The safety and effectiveness of NovoThirteen in 6 children below 6 years of age was supported by data from a long-term study during which the patients were given NovoThirteen to prevent bleeding. No bleeding episodes occurred in children treated with NovoThirteen.

A further study followed up 30 patients receiving NovoThirteen for prevention. In 6 bleeding episodes resulting from injury and requiring use of a factor XIII medicine, 5 were treated with single doses of NovoThirteen with good results. Bleeding was also kept satisfactorily under control in a patient given single doses of NovoThirteen before two minor surgeries.

What are the risks associated with NovoThirteen?

The most common side effect with NovoThirteen (which may affect more than 1 in 3 people) is headache. Other common side effects (which may affect up to 1 in 10 people) are leucopenia (low white blood cell counts, including neutrophils which fight infections), pain in the arms and legs, injection site pain, and the presence in the blood of antibodies that attach to factor XIII and of small protein fragments called 'fibrin D-dimer'.

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

Why is NovoThirteen authorised in the EU?

The main study provided satisfactory results on the effectiveness of preventative long-term use of NovoThirteen in congenital factor XIII A-subunit deficiency, since no severe or life-threatening bleedings occurred during treatment. Also, in patients already receiving preventative treatment, single use of NovoThirteen was effective for treating episodes of bleeding. No major side effects were seen with long term use of NovoThirteen.

The European Medicines Agency therefore decided that NovoThirteen'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 NovoThirteen?

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

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

Other information about NovoThirteen

NovoThirteen received a marketing authorisation valid throughout the EU on 3 September 2012.

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

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