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Coagadex (*human coagulation factor X*)

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

What is Coagadex and what is it used for?

Coagadex is a medicine used for the treatment and prevention of bleeding (including during and after an operation) in patients with hereditary factor X deficiency. Factor X deficiency is a bleeding disorder caused by lack of factor X, a protein needed for normal clotting of the blood.

Factor X deficiency is rare and Coagadex was designated an 'orphan medicine' (a medicine used in rare diseases) on 14 September 2007. Further information on the orphan designation can be found here: ema.europa.eu/Find medicine/Human medicines/Rare disease designation

Coagadex contains the active substance human coagulation factor X.

How is Coagadex used?

Coagadex is given by injection into a vein. The dose and frequency of the injections depend on the severity of the patient's factor X deficiency, the extent and location of the bleeding and the patient's condition and bodyweight.

Coagadex can only be obtained with a prescription and treatment should be started under the supervision of a doctor experienced in the treatment of rare bleeding disorders. Patients may inject Coagadex themselves at home once they have been trained appropriately. For more information about using Coagadex, see the package leaflet or contact your doctor or pharmacist.

How does Coagadex work?

Patients with hereditary factor X deficiency lack factor X, a protein needed to form the blood clot that stops wounds from bleeding. In these patients, blood clots do not form properly, resulting in bleeding that does not stop easily and poor wound healing. The active substance in Coagadex is human factor X isolated from the plasma of blood donors. By replacing the missing factor X, Coagadex helps the blood to clot and gives temporary control of bleeding.

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What benefits of Coagadex have been shown in studies?

Coagadex has been investigated in one main study involving 16 patients with hereditary factor X deficiency aged 12 to 58 years. Patients received Coagadex either to treat any spontaneous bleeding during the treatment period or to prevent bleeding during surgery. The main measure of effectiveness was based on the doctor's and patient's assessment of how well the treatment worked in preventing and treating bleeding episodes.

For the treatment of bleeding, 187 bleeding episodes were recorded and assessed, and treatment with Coagadex was rated as 'excellent' or 'good' for 98.4% of bleeding episodes. For 3 minor surgeries during the study, Coagadex was rated as excellent in preventing bleeding episodes.

In a study with 9 children aged less than 12 years (4 of whom were under4 years of age), a routine preventive treatment with Coagadex over 6 months was rated as excellent in reducing or preventing bleeding episodes. In total, 10 bleeds were reported in the study, of which 4 were treated with Coagadex. A single infusion of Coagadex was sufficient to control each treated bleeding event.

What are the risks associated with Coagadex?

The most common side effects with Coagadex (which may affect up to 1 in 10 people) are pain or redness at the injection site, fatigue (tiredness), and back pain.

Hypersensitivity (allergic) reactions can occur rarely in patients treated for bleeding disorders (in up to 1 patient in 1,000) and can be severe in some cases. These reactions have not been reported during clinical studies with Coagadex.

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

Why is Coagadex authorised in the EU?

The European Medicines Agency decided that the benefits of Coagadex are greater than its risks and it can be authorised for use in the EU. The Agency considered the lack of specific therapies for factor X deficiency, and concluded that Coagadex was effective at treating and preventing bleeding in patients with the condition. The side effects of Coagadex were considered manageable and of mild or moderate intensity. However, given the extreme rarity of the condition, the safety database is small and rare events are not expected to be captured during the clinical studies.

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

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

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

Other information about Coagadex

Coagadex received a marketing authorisation valid throughout the EU on 16 March 2016.

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

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