21 July 2016
EMA/CHMP/482423/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Inhixa

enoxaparin sodium

On 21 July 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Inhixa, intended for prevention and treatment of various disorders related to blood clots in adults. The applicant for this medicinal product is Techdow Europe AB.

Inhixa will be available as a solution for injection [2,000 IU (20 mg) in 0.2 mL, 4,000 IU (40 mg) in 0.4 mL, 6,000 IU (60 mg) in 0.6 mL, 8,000 IU (80 mg) in 0.8 mL and 10,000 IU (100 mg) in 1 mL]. The active substance of Inhixa is enoxaparin sodium, an antithrombotic agent (ATC code: B01AB05). Enoxaparin sodium is a low-molecular weight heparin that has a high activity against the blood clotting factor Xa and a low anti-factor IIa or antithrombin activity.

The benefits with Inhixa are its ability to treat blood clots formed in blood vessels and to stop blood clots forming in blood vessels.

The most common side effect is haemorrhage which can be severe and in some cases fatal. Other adverse reactions include thrombocytopenia (including immuno-allergic thrombocytopenia), allergic reactions (including anaphylactic /anaphylactoid reaction), hyperkalaemia, injection site reactions, increased hepatic enzymes, hepatitis, skin and subcutaneous disorders (urticaria, pruritus, erythema bullous dermatitis) and osteoporosis (following long-term therapy).

The full indication is:

> "Inhixa is indicated for adults for:
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> Prophylaxis of venous thromboembolism, particularly in patients undergoing orthopaedic, general or oncological surgery.
>
> Prophylaxis of venous thromboembolism in patients bedridden due to acute illnesses including acute heart failure, acute respiratory failure, severe infections, as well as exacerbation of rheumatic diseases causing immobilisation of the patient (applies to strengths of 40 mg/0.4 mL).
>
> Treatment of deep vein thrombosis (DVT), complicated or uncomplicated by pulmonary embolism.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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Treatment of unstable angina and non Q wave myocardial infarction, in combination with acetylsalicylic acid (ASA).

Treatment of acute ST segment elevation myocardial infarction (STEMI) including patients who will be treated conservatively or who will later undergo percutaneous coronary angioplasty (applies to strengths of 60 mg/0.6 mL, 80 mg/0.8 mL, and 100 mg/1 mL).

Blood clot prevention in the extracorporeal circulation during haemodialysis."

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.