19 November 2015
EMA/CHMP/721224/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Eptifibatide Accord

eptifibatide

On 19 November 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Eptifibatide Accord, intended for the prevention of early myocardial infarction in adults presenting with unstable angina or non-Q-wave myocardial infarction. The applicant for this medicinal product is Accord Healthcare Limited.

Eptifibatide Accord will be available as a 0.75 mg/ml solution for infusion and a 2 mg/ml solution for injection. The active substance of Eptifibatide Accord is eptifibatide, an antithrombotic agent (ATC code: B01AC16). It stops the platelets aggregating by blocking a protein called glycoprotein IIb/III on their surface. Eptifibatide Accord reduces the risk of a blood clot forming and helps prevent another heart attack.

Eptifibatide Accord is a generic of Integrilin, which has been authorised in the EU since 1 July 1991. As Eptifibatide Accord is administered intravenously and is 100% bioavailable, a bioequivalence study versus the reference product Integrilin was not required.

The full indication is:

“Eptifibatide Accord is intended for use with acetylsalicylic acid and unfractionated heparin.”

Eptifibatide Accord is indicated for the prevention of early myocardial infarction in adults presenting with unstable angina or non-Q-wave myocardial infarction, with the last episode of chest pain occurring within 24 hours and with electrocardiogram (ECG) changes and/or elevated cardiac enzymes.

Patients most likely to benefit from Eptifibatide Accord treatment are those at high risk of developing myocardial infarction within the first 3-4 days after onset of acute angina symptoms including for instance those that are likely to undergo an early PTCA (Percutaneous Transluminal Coronary Angioplasty) (see section 5.1).”

Eptifibatide Accord should be administered by specialist physicians experienced in the management of acute coronary syndromes.

[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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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.