20 September 2012
EMA/CHMP/513131/2012
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Ibandronic acid Accord

ibandronic acid

On 20 September 2012 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ibandronic acid Accord 2 mg and 6 mg Concentrate for Solution for Infusion intended for the prevention of skeletal events (pathological fractures, bone complications requiring radiotherapy or surgery) in patients with breast cancer and bone metastases, and treatment of tumour-induced hypercalcaemia with or without metastases. The applicant for this medicinal product is Accord Healthcare Limited. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Ibandronic acid Accord is ibandronic acid a third generation bisphosphonate (ATC Code: M05BA06) which inhibits bone resorption.

Ibandronic Acid Accord is a generic of Bondronat which has been authorised in the EU since 22 June 1996. Studies have demonstrated the satisfactory quality of Ibandronic acid Accord. Ibandronic acid Accord is administered intravenously and is 100% bioavailable, therefore, a bioequivalence study versus the reference product Bondronat was not required. A question-and-answer document on generic medicines can be found here.

A pharmacovigilance plan for Ibandronic acid Accord will be implemented as part of the marketing authorisation.

The approved indication is: prevention of skeletal events (pathological fractures, bone complications requiring radiotherapy or surgery) in patients with breast cancer and bone metastases, and treatment of tumour-induced hypercalcaemia with or without metastases. It is proposed that Ibandronic acid Accord is prescribed by physicians experienced in the treatment of cancer.

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

[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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will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Ibandronic acid Accord and therefore recommends the granting of the marketing authorisation.