



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

17 February 2011  
EMA/112994/2011  
Committee for medicinal products for human use (CHMP)

## **Summary of opinion<sup>1</sup> (initial authorisation)**

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### **Ibandronic Acid Sandoz**

ibandronic acid

On 17 February 2011 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 Sandoz 50mg film-coated tablets intended for prevention of skeletal events in patients with breast cancer and bone metastases. The applicant for this medicinal product is Sandoz Pharmaceuticals GmbH. They may request a re-examination of the CHMP opinion, provided that 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 Sandoz is ibandronic acid, a third generation bisphosphonate (ATC Code: M05B A 06) which inhibits bone resorption.

Ibandronic Acid Sandoz is a generic of Bondronat which has been authorised in the EU since 25 June 1996. Studies have demonstrated the satisfactory quality of Ibandronic Acid Sandoz, and its bioequivalence with Bondronat. A question-and-answer document on generic medicines can be found [here](#).

The approved indication for 50mg film-coated tablets is: "Prevention of skeletal events (pathological fractures, bone complications requiring radiotherapy or surgery) in patients with breast cancer and bone metastases".

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 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 Sandoz and therefore recommends the granting of the marketing authorisation.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.

