21 October 2010
EMA/643636/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Iasibon

ibandronic acid

On 21 October 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Iasibon 50mg film-coated tablets intended for prevention of skeletal events in patients with breast cancer and bone metastases and Iasibon 1 mg/ml, 2 mg/2ml, 6 mg/6ml concentrate for solution for infusion intended for prevention of skeletal events 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 Pharmathen S.A.

The active substance of Iasibon is ibandronic acid, a third generation bisphosphonate (ATC Code: M05B A 06) which inhibits bone resorption.

Iasibon is a generic of Bondronat which has been authorised in the EU since 25 June 1996. Studies have demonstrated the satisfactory quality of Iasibon, 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".

The approved indication for concentrate for solution for infusion is: "Prevention of skeletal events (pathological fractures, bone complications requiring radiotherapy or surgery) in patients with breast cancer and bone metastases. Treatment of tumour-induced hypercalcaemia with or without 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.

[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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7<sector fax>
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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