EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Hexal AG withdraws its marketing authorisation application for Ibandronic acid Hexal

(ibandronic acid)

The European Medicines Agency has been formally notified by Hexal AG of its decision to withdraw its application for a centralised marketing authorisation for the medicine Ibandronic acid Hexal (ibandronic acid), 50 mg, film-coated tablets.

Ibandronic acid Hexal was originally intended to be used for the prevention of skeletal events in patients with breast cancer and bone metastases.

The application for the marketing authorisation for Ibandronic acid Hexal was submitted to the Agency on 6 December 2010 as a duplicate to Iasibon, 50 mg film-coated tablets, which was authorised on 21 January 2011. The Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for this medicine on 17 February 2011. At the time of withdrawal the medicine had been sent to the European Commission (EC) for the adoption of the marketing authorisation.

In its official letter, the company stated that its decision to withdraw the application was based on the fact that the EC considers that the co-marketing reasons were not acceptable in this case.

More information about Ibandronic acid Hexal will be made available in a question-and-answer document. This document, together with the withdrawal letter from the company and the assessment report, will be published on the Agency's website in the second half of August 2011.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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