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Questions and answers

Withdrawal of the marketing authorisation application for Ibandronic Acid Hexal (ibandronic acid)

On 21 July 2011, Hexal AG officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Ibandronic Acid Hexal, for the prevention of skeletal events in patients with breast cancer and bone metastases.

What is Ibandronic Acid Hexal?

Ibandronic Acid Hexal is a medicine that contains the active substance ibandronic acid. It was to be available as white tablets.

Ibandronic Acid Hexal was developed as a 'generic medicine'. This means that Ibandronic Acid Hexal was intended to be similar to a 'reference medicine' already authorised in the European Union called Bondronat. For more information on generic medicines, see the question-and-answer document here.

What was Ibandronic Acid Hexal expected to be used for?

Ibandronic Acid Hexal was to be used to prevent 'skeletal events' (fractures [broken bones] or bone complications requiring treatment) in patients with breast cancer and bone metastases (when the cancer has spread to the bone).

How is Ibandronic Acid Hexal expected to work?

Ibandronic Acid Hexal is expected to work in the same way as the reference medicine, Bondronat. The active substance in Ibandronic Acid Hexal and Bondronat, ibandronic acid, is a bisphosphonate. It stops the action of the osteoclasts, the cells in the body that are involved in breaking down the bone tissue. This leads to less bone loss. The reduction of bone loss helps to make bones less likely to break, which is useful in preventing fractures in cancer patients with bone metastases.

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What did the company present to support its application?

Because Ibandronic Acid Hexal was developed as a generic medicine, the company presented the results of studies carried out to investigate whether it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

How far into the evaluation was the application when it was withdrawn?

The evaluation had finished and the CHMP had given a positive opinion. The company withdrew before the European Commission had issued a decision on this opinion.

What was the recommendation of the CHMP at that time?

The CHMP concluded that, in accordance with EU requirements, Ibandronic Acid Hexal had been shown to have comparable quality and to be bioequivalent to Bondronat. Therefore, the CHMP's view was that, as for Bondronat, the benefit outweighs the identified risk. The Committee recommended that Ibandronic Acid Hexal be given marketing authorisation.

What were the reasons given by the company for withdrawing the application?

The letter from the company notifying the Agency of the withdrawal of the application is available under the tab 'All documents'.