European Medicines Agency

London, 17 December 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION[*]
for
BONDRONAT

International Nonproprietary Name (INN): Ibandronic acid

On 17 December 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion[**] to recommend the variation to the terms of the marketing authorisation for the medicinal product Bondronat. The Marketing Authorisation Holder for this medicinal product is Roche Registration Ltd.

The CHMP adopted new contraindications for Bondronat.
The following contraindication was added for both the 50 mg film-coated tablets and the concentrate for solution for infusion: "*hypocalcaemia*"

In addition the following contraindication has been added for 50 mg film-coated tablets only:
"- Abnormalities of the oesophagus which delay oesophageal emptying such as stricture or achalasia
- Inability to stand or sit upright for at least 60 minutes"

Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) which will be published in the revised European Public Assessment Report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full contraindications for Bondronat concentrate for solution for infusion will be as follows[****]:
*"**Hypocalcaemia (see section 4.4).***
Hypersensitivity to the active substance or to any of the excipients.
Caution is to be taken in patients with known hypersensitivity to other bisphosphonates.
Bondronat should not be used in children."

For information, the full contraindications for Bondronat 50 mg film-coated tablets will be as follows[****]:
"-Abnormalities of the oesophagus which delay oesophageal emptying such as stricture or achalasia
- Inability to stand or sit upright for at least 60 minutes
- Hypocalcaemia
- Hypersensitivity to ibandronic acid or to any of the excipients
See also section 4.4.

Bondronat should not be used in children."

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[*] Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the Opinion.

[**] Marketing Authorisation Holders may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

[****] The text in bold represents the new or the amended contraindication.

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