European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 23 July 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
ALENDRONATE SODIUM AND COLECALCIFEROL, MSD

International Nonproprietary Name (INN): ***alendronic acid / colecalciferol***

On 23 July 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Alendronate Sodium and Colecalciferol, MSD, 70 mg / 2800 IU, 70 mg / 5600 IU, tablet intended for treatment of postmenopausal osteoporosis.
The applicant for this medicinal product is Merck Sharp & Dohme Ltd.

The active substance of ALENDRONATE Alendronate Sodium and Colecalciferol, MSD is a fixed dose combination of two active substances, alendronic acid (in the form of alendronate sodium trihydrate) and colecalciferol (vitamin D3), which is suitable for a once weekly regimen. Alendronate belongs to a group of non-hormonal medicines called bisphosphonates, which prevents the loss of bone that occurs in women after they have been through the menopause, and helps to rebuild bone. It reduces the risk of spine and hip fractures. Vitamin D is an essential nutrient, required for calcium absorption and healthy bones.

The benefits with Alendronate Sodium and Colecalciferol, MSD relate to the reduction of the risk of spine and hip fractures. The most common side effects relate to the digestive tract (including abdominal pain, pain upon swallowing, inflammation or ulceration of the gullet) as well as bone, muscle and/or joint pain

A pharmacovigilance plan for ALENDRONATE Alendronate Sodium and Colecalciferol, MSD, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: “treatment of postmenopausal osteoporosis in patients at risk of vitamin D insufficiency. Alendronate Sodium and Colecalciferol, MSD reduces the risk of vertebral and hip fractures”

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) 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 of the reference product FOSAVANCE, considers that there is a favourable benefit-risk balance for Alendronate Sodium and Colecalciferol, MSD and therefore recommends the granting of the marketing authorisation.

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants 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.

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