European Medicines Agency
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PRESS RELEASE
European Medicines Agency: Committee for Medicinal Products for Human Use 23-26 May 2005

The Committee for Medicinal Products for Human Use (CHMP) gave a positive opinion on an initial marketing authorisation for **Fosavance** (alendronic acid and colecalciferol) from Merck Sharp & Dohme Ltd. Fosavance is indicated for the treatment of postmenopausal osteoporosis in patients at risk of vitamin D insufficiency. EMEA review began on 18 October 2004 with an active review time of 182 days. A summary of opinion including the full indication for this product is available on the EMEA website: http://www.emea.eu.int

The CHMP adopted positive opinions on the extensions of indication for medicinal products that are already authorised in the European Union:

- **Arixtra** (fondaparinux) and **Quixidar** (fondaparinux), Glaxo Group Ltd, to include the prevention of venous thromboembolism (VTE) in patients undergoing abdominal surgery who are judged to be at high risk of thromboembolic complications, such as patients undergoing abdominal cancer surgery. Arixtra was first authorised in the European Union on 21 May 2002.
- **Cymbalta** (duloxetine), Eli Lilly Nederland B.V., and **Xeristar** (duloxetine), Boehringer Ingelheim International GmbH, to extend their use to the treatment of diabetic peripheral neuropathic pain. Cymbalta and Xeristar were first authorised in the European Union on 17 December 2004.
- **Invanz** (ertapenem), Merck Sharp & Dohme, to extend its use to include children from 3 months to 17 years of age. Invanz is currently indicated for the treatment of the following bacterial infections in adults: intra-abdominal infections, community acquired pneumonia and acute gynaecological infections. The product was first authorised in the European Union on 18 April 2002.

The CHMP adopted an opinion to recommend the update of the contraindications for **Invirase** (saquinavir mesylate) and **Fortovase** (saquinavir) from Roche Registration Ltd.

Summaries of opinion for these medicinal products are available on the EMEA website: http://www.emea.eu.int

The CHMP began an arbitration review for **Prozac** (fluoxetine) and associated trade names, following an application by Eli Lilly to extend the indication to include the treatment of major depressive episodes in children and adolescents. The review was initiated by France on the basis of safety and efficacy concerns raised by a number of Member States concerning the use of Prozac in this age group. The arbitration is made under Article 6(12) of Commission Regulation (EC) No 1084/2003.

Prozac is authorised in most EU Member States for the treatment of major depressive episodes, obsessive-compulsive disorder and bulimia nervosa in adults. The CHMP advised in April 2005 that the class of serotonin selective re-uptake inhibitors (SSRI) medicines, including fluoxetine, should not be used in children and adolescents except in their approved indications. The April 2005 statement, including advice for prescribers, patients and parents, is available on the EMEA website and can be found here.

A more detailed CHMP meeting report will be published shortly.

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