15 March 2012
EMA/176371/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zoledronic Acid Teva Pharma

Zoledronic acid

On 15 March 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zoledronic Acid Teva Pharma, 5 mg, solution for infusion intended for the treatment of osteoporosis (in post-menopausal women and in men at increased risk of fracture), treatment of osteoporosis associated with long-term systemic glucocorticoid therapy (in post-menopausal women and in men at increased risk of fracture) and for the treatment of Paget's disease of the bone in adults.

The applicant for this medicinal product is Teva Pharma B.V. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Zoledronic Acid Teva Pharma is zoledronic acid (as monohydrate), a bisphosphonate (M05BA08). Zoledronic acid acts primarily on the bone; it is an inhibitor of osteoclast-mediated bone resorption. The selective action of bisphosphonates on bone is based on their high affinity for mineralised bone. Zoledronic acid treatment rapidly reduces the rate of bone turnover. The positive effect of zoledronic acid on various types of bone fractures, bone mineral density, bone histology, bone turnover markers, standing height and days of disability was demonstrated in patients with osteoporosis. In Paget's disease, bone of normal quality was found in responding patients after treatment with zoledronic acid.

The most common side effects are fever, myalgia, flu-like symptoms, arthralgia and headache.

Zoledronic acid Teva Pharma is a generic of Aclasta, which has been authorised in the EU since 15 April 2005. Studies have demonstrated the satisfactory quality of Zoledronic acid Teva Pharma. This product is administered intravenously and is 100% bioavailable; therefore, a bioequivalence study versus the reference product Aclasta was not required. A question and answer document on generic medicines can be found here.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7<sector fax>
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

A pharmacovigilance plan for Zoledronic Acid Teva Pharma will be implemented as part of the marketing authorisation.

The approved indication is:

Treatment of osteoporosis
- in post-menopausal women
- in men

at increased risk of fracture

Treatment of osteoporosis associated with long-term systemic glucocorticoid therapy
- in post-menopausal women
- in men

at increased risk of fracture

Treatment of Paget's disease of the bone in adults

It is proposed that for the treatment of Paget's disease, Zoledronic acid Teva Pharma be prescribed only by physicians with experience in the treatment of Paget's disease of the bone.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made 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 submitted, considers there to be a favourable benefit-to-risk balance for Zoledronic Acid Teva Pharma and therefore recommends the granting of the marketing authorisation.