15 March 2012
EMA/193393/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zoledronic Acid Teva

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 4mg/5ml solution for infusion, intended for the prevention of skeletal related events in adult patients with advanced malignancies involving bone and for the treatment of adult patients with tumour-induced hypercalcaemia.

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 this generic medical product is zoledronic acid, a bisphosphonate (M05BA08), that acts primarily on bone. It is an inhibitor of osteoclastic bone resorption. The selective action of bisphosphonates on bone is based on their high affinity for mineralised bone, but the precise molecular mechanism leading to the inhibition of osteoclastic activity is still unclear. In addition to being a potent inhibitor of bone resorption, zoledronic acid also possesses several anti-tumour properties that could contribute to its overall efficacy in the treatment of metastatic bone disease.

Patients with tumors can have high levels of calcium in their blood, released from the bones. By preventing the breakdown of bones, Zoledronic acid also helps to reduce the amount of calcium released into the blood.

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

Zoledronic acid Teva is a generic of Zometa, which has been authorised in the EU since 15 April 2005. Studies have demonstrated the satisfactory quality of Zoledronic acid Teva. This product is administered intravenously and is 100% bioavailable; therefore, a bioequivalence study versus the reference product Zometa 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.

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

The approved indication is:

- prevention of skeletal related events (pathological fractures, spinal compression, radiation or surgery to bone, or tumour-induced hypercalcaemia) in adult patients with advanced malignancies involving bone
- treatment of adult patients with tumour-induced hypercalcaemia (TIH).

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 and therefore recommends the granting of the marketing authorisation.