24 May 2012
EMA/CHMP/271157/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zoledronic acid medac

zoledronic acid

On 24 May 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 medac, 4mg/5ml concentrate for solution for infusion and 4mg/100ml solution for infusion intended for the 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, and the treatment of adult patients with tumour-induced hypercalcaemia (TIH).

The applicant for this medicinal product is medac Gesellschaft für klinische Spezialpräparate mbH.

The active substance of Zoledronic acid medac is zoledronic acid (as monohydrate), a bisphosphonate (M05BA08). Zoledronic acid stops the action of the osteoclasts, the cells in the body that are involved in breaking down the bone tissue. This leads to less bone loss. The reduction of bone loss helps to make bones less likely to break, which is useful in preventing fractures in cancer patients with bone metastases. Patients with tumours 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.

Zoledronic acid medac is a generic of Zometa, which has been authorised in the EU since 20 March 2001. Studies have demonstrated the satisfactory quality of Zoledronic acid medac. 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.

A pharmacovigilance plan for Zoledronic acid medac will be implemented as part of the marketing authorisation.

[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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The approved indications are:

- “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.
- The treatment of adult patients with tumour-induced hypercalcaemia (TIH)”.

Zoledronic acid medac must only be prescribed and administered to patients by healthcare professionals experienced in the administration of intravenous biphosphonates.

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 medac and therefore recommends the granting of the marketing authorisation.