20 September 2012
EMA/CHMP/604898/2012
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Zoledronic Acid Hospira

zoledronic acid

On 20 September 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 Hospira 4 mg /5 ml and 4 mg/ 100 ml in 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.
- Treatment of adult patients with tumour-induced hypercalcaemia (TIH)

and Zoledronic Acid Hospira 5 mg/ 100 ml in the:

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

  at increased risk of fracture, including those with a recent low-trauma hip 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.

The applicant for this medicinal product is Hospira UK Ltd. 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 Hospira is zoledronic acid, 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.

[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 7418 8545
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

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 Hospira is a generic of Zometa and Aclasta, which have been authorised in the EU since 20/03/2001 (Zometa) and 15 April 2005 (Aclasta). Studies have demonstrated the satisfactory quality of Zoledronic Acid Hospira. This product is administered intravenously and is 100% bioavailable; therefore, a bioequivalence study versus the reference product Zometa or Aclasta was not required. A question and answer document on generic medicines can be found here.

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

The approved indication is:

Zoledronic acid Hospira 4 mg /5 ml and 4 mg/ 100 ml:

- 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).

Zoledronic acid Hospira 5 mg/ 100 ml:

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

  at increased risk of fracture, including those with a recent low-trauma hip 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 Zoledronic Acid Hospira 4 mg /5 ml and 4 mg/ 100 ml is prescribed by healthcare professionals experienced in the administration of intravenous biphosphonates.

It is proposed that for the treatment of Paget's disease, Zoledronic acid Hospira 5 mg/ 100 ml is 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 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 submitted, considers there to be a favourable benefit to risk balance for Zoledronic Acid Hospira and therefore recommends the granting of the marketing authorisation.