



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 June 2010
EMA/CHMP/390850/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion¹ (initial authorisation)

Ibandronic Acid Teva

ibandronic acid

On 24 June 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ibandronic Acid Teva 50mg and 150mg film-coated tablets intended for the prevention of skeletal events in patients with breast cancer and bone metastases (50mg) and the treatment of osteoporosis in postmenopausal women at increased risk of fracture (150mg). 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 Ibandronic Acid Teva is ibandronic acid, third generation bisphosphonate which inhibits bone resorption.

The approved indication is: "Ibandronic Acid Teva is indicated for the prevention of skeletal events (pathological fractures, bone complications requiring radiotherapy or surgery) in patients with breast cancer and bone metastases" for the 50mg and "Treatment of osteoporosis in postmenopausal women at increased risk of fracture (see section 5.1). A reduction in the risk of vertebral fractures has been demonstrated, efficacy on femoral neck fractures has not been established" for the 150mg.

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 Ibandronic Acid Teva and therefore recommends the granting 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.

