21 July 2011
EMA/CHMP/587645/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Zytiga

abiraterone

On 21 July 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zytiga 250mg tablet, intended for the treatment of metastatic castration resistant prostate cancer. The applicant for this medicinal product is Janssen-Cilag International N.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 Zytiga is abiraterone acetate, a hormone antagonist and related agent (L02BX03) that inhibits the production of androgens in the testes, adrenal glands and overall.

The benefits with Zytiga are its ability to improve the survival of patients and to delay the progression of disease. The most common side effects are peripheral oedema, hypokalaemia, hypertension and urinary tract infection.

A pharmacovigilance plan for Zytiga will be implemented as part of the marketing authorisation.

The approved indication is: “Zytiga is indicated with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen”.

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 Zytiga 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.

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