15 November 2012
EMA/CHMP/697344/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Zytiga

abiraterone

On 15 November 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Zytiga. The marketing authorisation holder for this medicinal product is Janssen-Cilag International N V. They may request a re examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a new indication as follows:
"ZYTIGA is indicated with prednisone or prednisolone for: the treatment of metastatic castration resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated".

The CHMP adopted a new contraindication as follows:
"Severe hepatic impairment (Child-Pugh Class C)".

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indication for Zytiga will be as follows[2]:

ZYTIGA is indicated with prednisone or prednisolone for:

- **the treatment of metastatic castration resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated**
- the treatment of metastatic castration resistant prostate cancer in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.
[2] The text in bold represents the new or the amended indication.

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