25 February 2021
EMA/CHMP/101446/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Abiraterone Accord

abiraterone

On 25 February 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Abiraterone Accord, intended for the treatment of metastatic prostate cancer. The applicant for this medicinal product is Accord Healthcare S.L.U.

Abiraterone Accord will be available as 250-mg tablet and 500-mg film-coated tablet. The active substance of Abiraterone Accord is abiraterone (as abiraterone acetate), a hormone antagonist (ATC code: L02BX03) that inhibits the production of androgens in the testes, adrenal glands and prostatic tumour tissues.

Abiraterone Accord is a generic of Zytiga, which has been authorised in the EU since 05/09/2011. Studies have demonstrated the satisfactory quality of Abiraterone Accord, and its bioequivalence to the reference product Zytiga. A question and answer document on generic medicines can be found here.

The full indication is:

Abiraterone Accord is indicated with prednisone or prednisolone for:

- the treatment of newly diagnosed high risk metastatic hormone sensitive prostate cancer (mHSPC) in adult men in combination with androgen deprivation therapy (ADT)
- the treatment of metastatic castration resistant prostate cancer (mCRPC) 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 mCRPC in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen.

Abiraterone Accord should be prescribed by an appropriate healthcare professional.

Detailed recommendations for the use of this product will be described in the summary of product

[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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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.