22 April 2021
EMA/CHMP/211070/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Abiraterone KRKA

abiraterone acetate

On 22 April 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 KRKA, intended for the treatment of metastatic prostate cancer.

The applicant for this medicinal product is KRKA, d.d., Novo mesto.

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

Abiraterone KRKA is a generic of Zytiga, which has been authorised in the EU since 05/09/2011. Studies have demonstrated the satisfactory quality of Abiraterone KRKA, 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 KRKA 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 KRKA should be prescribed by an appropriate healthcare professional.

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

[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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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.