27 June 2024
EMA/270183/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Enzalutamide Viatris

enzalutamide

On 27 June 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Enzalutamide Viatris, intended for the treatment of prostate cancer. The applicant for this medicinal product is Viatris Limited.

Enzalutamide Viatris will be available as 40 mg and 80 mg film-coated tablets. The active substance of Enzalutamide Viatris is enzalutamide, a hormone antagonist (ATC code: L02BB04) that blocks several steps in the androgen receptor-signalling pathway.

Enzalutamide Viatris is a generic of Xtandi, which has been authorised in the EU since 21 June 2013. Studies have demonstrated the satisfactory quality of Enzalutamide Viatris, and its bioequivalence to the reference product Xtandi. A question and answer document on generic medicines can be found here.

The full indication is:

Enzalutamide Viatris is indicated:

- as monotherapy or in combination with androgen deprivation therapy for the treatment of adult men with high-risk biochemical recurrent (BCR) non-metastatic hormone-sensitive prostate cancer (nmHSPC) who are unsuitable for salvage-radiotherapy (see section 5.1).
- in combination with androgen deprivation therapy for the treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC) (see section 5.1).
- for the treatment of adult men with high-risk non-metastatic castration-resistant prostate cancer (CRPC) (see section 5.1).
- for the treatment of adult men with metastatic CRPC who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated (see section 5.1).

[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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- for the treatment of adult men with metastatic CRPC whose disease has progressed on or after docetaxel therapy.

Enzalutamide Viatris should be prescribed by physicians experienced in the treatment of prostate cancer.

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