13 November 2025
EMA/245975/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Enzalutamide Accordpharma

enzalutamide

On 13 November 2025, 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 Accordpharma, intended for the treatment of prostate cancer.

The applicant for this medicinal product is Accord Healthcare S.L.U.

Enzalutamide Accordpharma will be available as 40 mg, 80 mg and 160 mg film-coated tablets. The active substance of Enzalutamide Accordpharma is enzalutamide, a hormone antagonist (ATC code: L02BB04) that blocks several steps in the androgen receptor-signalling pathway.

Enzalutamide Accordpharma is a generic and hybrid[2] of Xtandi, which has been authorised in the EU since 21 June 2013. Studies have demonstrated the satisfactory quality of Enzalutamide Accordpharma, 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 Accordpharma is indicated:
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> - 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).

[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
[2] Hybrid applications rely in part on results of pre-clinical tests and clinical trials for a reference product and in part on new data

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

Treatment with Enzalutamide Accordpharma should be initiated and supervised by specialist physicians experienced in the medical 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 on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.