



21 March 2024
EMA/CHMP/87028/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Xtandi enzalutamide

On 21 March 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Xtandi. The marketing authorisation holder for this medicinal product is Astellas Pharma Europe B.V.

The CHMP adopted a new indication for the treatment of adult men with high-risk biochemical recurrent (BCR) non-metastatic hormone-sensitive prostate cancer. For information, the full indications for Xtandi will be as follows:²

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

Detailed recommendations 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

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 New text in **bold**



(EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.