



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 September 2018
EMA/CHMP/638103/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Xtandi

enzalutamide

On 20 September 2018, 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 as follows:

"treatment of adult men with high-risk non-metastatic castration-resistant prostate cancer".

For information, the full indications for Xtandi will be as follows:²

"Xtandi is indicated for:

- **the treatment of adult men with high-risk non-metastatic castration-resistant prostate cancer (CRPC) (see section 5.1).**
- 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).
- 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 (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.

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

