29 January 2026
EMADOC-1700519818-2853904
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Akeega

niraparib / abiraterone acetate

On 29 January 2026, 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 Akeega. The marketing authorisation holder for this medicinal product is Janssen-Cilag International NV.

The CHMP adopted a new indication as follows:[2]

Akeega is indicated with prednisone or prednisolone:

- **in combination with androgen deprivation therapy (ADT) for the treatment of adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) and BRCA 1/2 mutations (germline and/or somatic).**
- for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC) and BRCA 1/2 mutations (germline and/or somatic) in whom chemotherapy is not clinically indicated.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website 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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union