30 April 2020
EMA/CHMP/200669/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Cabazitaxel Accord

cabazitaxel

On 30 April 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Cabazitaxel Accord, intended for the treatment of patients with hormone refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen. The applicant for this medicinal product is Accord Healthcare S.L.U.

Cabazitaxel Accord will be available as a 20 mg/ml concentrate for solution for infusion. The active substance of Cabazitaxel Accord is cabazitaxel, an antineoplastic agent (ATC code: L01CD04) that acts by disrupting the microtubular network in cells. It binds to tubulin and promotes the assembly of tubulin into microtubules, while simultaneously inhibiting their disassembly. This stabilises microtubules, which results in the inhibition of mitotic and interphase cellular functions.

Cabazitaxel Accord is a hybrid medicine[2] of Jevtana which has been authorised in the EU since 17 March 2011. Cabazitaxel Accord contains the same active substance as Jevtana, but it is available in a different formulation.

Studies have demonstrated the satisfactory quality of Cabazitaxel Accord, and its bioequivalence to the reference product Jevtana. Since Cabazitaxel Accord is administered intravenously and is 100% bioavailable, a bioequivalence study was not required.

The full indication is:

> Cabazitaxel Accord in combination with prednisone or prednisolone is indicated for the treatment of adult patients with metastatic castration resistant prostate cancer previously treated with a docetaxel containing regimen.

It is proposed that Cabazitaxel Accord be prescribed by physicians experienced in the use of anticancer chemotherapy.

Detailed recommendations for the use of this product will be described in the summary of product

[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 the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

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

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.