20 January 2011
EMA/26276/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Jevtana

cabazitaxel

On 20 January 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Jevtana 60 mg concentrate and solvent for solution for infusion intended for patients with hormone refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen. The applicant for this medicinal product is Sanofi-aventis. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Jevtana is cabazitaxel, an antineoplastic agent (ATC code not yet assigned) that acts by disrupting the microtubular network in cells. Cabazitaxel binds to tubulin and promotes the assembly of tubulin into microtubules while simultaneously inhibiting their disassembly. This leads to the stabilisation of microtubules, which results in the inhibition of mitotic and interphase cellular functions.

The benefit with Jevtana in combination with prednisone is in terms of overall survival in patients with hormone refractory metastatic prostate cancer as observed in a clinical trial comparing Jevtana+prednisone against mitoxantrone+prednisone. The most common side effects are diarrhoea, fatigue, nausea, vomiting and neutropenia.

A pharmacovigilance plan for Jevtana will be implemented as part of the marketing authorisation.

The approved indication is: "Jevtana in combination with prednisone or prednisolone is indicated for the treatment of patients with hormone refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen."

It is proposed that Jevtana is prescribed by physicians experienced in the administration of anticancer chemotherapy.

[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.

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR), and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Jevtana and therefore recommends the granting of the marketing authorisation.