21 October 2010
EMA/CHMP/630633/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Docetaxel Teva Pharma

docetaxel

On 21 October 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product, Docetaxel Teva Pharma 40 mg/ml, concentrate and solvent for solution for infusion intended for breast cancer, non-small lung cancer and prostate cancer. The applicant for this medicinal product is Teva Pharma B.V. 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 Docetaxel Teva Pharma is docetaxel, an antineoplastic medicinal product (L01CD 02) that disrupts intracellular structures necessary for the replication and survival of cells (cytotoxic activity).

The benefits with Docetaxel Teva Pharma are its broad clinical anti-tumour activity against various tumour types. The most common side effects are neutropenia, anaemia, alopecia, nausea, vomiting, stomatitis, diarrhoea and asthenia.

The approved indications are:

Breast cancer

"Docetaxel Teva Pharma monotherapy is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic therapy. Previous chemotherapy should have included an anthracycline or an alkylating agent".

Non-small cell lung cancer

"Docetaxel Teva Pharma is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of prior 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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"Docetaxel Teva Pharma in combination with cisplatin is indicated for the treatment of patients with unresectable, locally advanced or metastatic non-small cell lung cancer, in patients who have not previously received chemotherapy for this condition".

Prostate cancer

"Docetaxel Teva Pharma in combination with prednisone or prednisolone is indicated for the treatment of patients with hormone refractory metastatic prostate cancer".

It is proposed that Docetaxel Teva Pharma should only be administered under the supervision of a physician qualified in the use of anticancer chemotherapy.

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 Docetaxel Teva Pharma and therefore recommends the granting of the marketing authorisation.