European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 19 November 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
DOCETAXEL TEVA

International Nonproprietary Name (INN): ***docetaxel***

On 19 November 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Docetaxel Teva, 40 mg/ml, concentrate and solvent for solution for infusion intended for Breast cancer, Prostate cancer, Gastric adenocarcinoma, Head and neck cancer. The applicant for this medicinal product is Teva Pharmaceuticals Europe B.V.

The active substance of Docetaxel Teva 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 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.

A pharmacovigilance plan for Docetaxel Teva, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is:

"Breast cancer

Docetaxel Teva in combination with doxorubicin and cyclophosphamide is indicated for the adjuvant treatment of patients with operable node-positive breast cancer.

Docetaxel Teva in combination with doxorubicin is indicated for the treatment of patients with locally advanced or metastatic breast cancer who have not previously received cytotoxic therapy for this condition.

Docetaxel Teva 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.

Docetaxel Teva in combination with trastuzumab is indicated for the treatment of patients with metastatic breast cancer whose tumors overexpress HER2 and who previously have not received chemotherapy for metastatic disease.

Docetaxel Teva in combination with capecitabine is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic chemotherapy. Previous therapy should have included an anthracycline.

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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Non-small cell lung cancer

Docetaxel Teva is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of prior chemotherapy.

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

Gastric adenocarcinoma

Docetaxel Teva in combination with cisplatin and 5-fluorouracil is indicated for the treatment of patients with metastatic gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior chemotherapy for metastatic disease.

Head and neck cancer

Docetaxel Teva in combination with cisplatin and 5-fluorouracil is indicated for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck.".

It is proposed that Docetaxel Teva 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 (SPC) 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 that there is a favourable benefit to risk balance for Docetaxel Teva and therefore recommends the granting of the marketing authorisation.