17 November 2011
EMA/CHMP/858298/2011
Committee for Medicinal Products for Human use (CHMP)

Summary of opinion[1] (initial authorisation)

Docetaxel Mylan

Docetaxel

On 17 November 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 Docetaxel Mylan, 20 mg/ml, concentrate for solution for infusion, intended for the treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma and head and neck cancer. The applicant for this medicinal product is Mylan S.A.S. 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 Mylan is docetaxel, an antineoplastic medicinal product (L01CD 02) that disrupts intracellular structures necessary for the replication and survival of cells (cytotoxic activity).

Docetaxel Mylan is a generic of Taxotere, which has been authorised in the EU since 27 November 1995. Studies have demonstrated the satisfactory quality of Docetaxel Mylan. A bioequivalence study versus the reference product Taxotere was not required. A question and answer document on generic medicines can be found here.

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

The approved indication is:

Breast cancer

Docetaxel Mylan in combination with doxorubicin and cyclophosphamide is indicated for the adjuvant treatment of patients with:

operable node-positive breast cancer

operable node-negative breast cancer

[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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7<sector fax>
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

For patients with operable node-negative breast cancer, adjuvant treatment should be restricted to patients eligible to receive chemotherapy according to internationally established criteria for primary therapy of early breast cancer (see section 5.1).

Docetaxel Mylan 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 Mylan 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 Mylan in combination with trastuzumab is indicated for the treatment of patients with metastatic breast cancer whose tumours over express HER2 and who previously have not received chemotherapy for metastatic disease.

Docetaxel Mylan 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.

Non-small cell lung cancer

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

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

Gastric adenocarcinoma

Docetaxel Mylan 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 Mylan 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 Mylan 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 Mylan and therefore recommends the granting of the marketing authorisation.