



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Development and Evaluation

Public statement on

Docefrez (Docetaxel)

Withdrawal of the marketing authorisation in the European Union

On 10 May 2010 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Docefrez (docetaxel), which had been approved for the following indications:

Breast cancer

Docetaxel 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.

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



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

Gastric adenocarcinoma

Docetaxel 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 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.

The Marketing Authorisation Holder (MAH) responsible for Docefrez was Sun Pharmaceutical Industries Europe B.V. The European Commission was notified by a letter dated 5 December 2011 of the MAH's decision to voluntarily withdraw the marketing authorisation as of the Commission Decision date for Docefrez for commercial reasons. Docefrez was only marketed in Germany.

On 25 May 2012 the European Commission issued a decision to withdraw the marketing authorisation for Docefrez.

Pursuant to this decision the European Public Assessment Report for Docefrez will be updated to reflect that the marketing authorisation is no longer valid.