EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 February 2012
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Press Office

Medicines granted a Community marketing authorisation under the centralised procedure

From 01 January 2012 to 31 January 2012

Invented name	**Efavirenz Teva**
INN	efavirenz
Marketing Authorisation Holder	Teva Pharma B.V.
Proposed ATC code	J05A G03
Indication	Treatment of human immunodeficiency virus-1 (HIV-1) infected adults, adolescents and children 3 years of age and older
CHMP opinion date	20/10/2011
Marketing authorisation date	09/01/2012

Invented name	**Desloratadine Actavis**
INN	desloratadine
Marketing Authorisation Holder	Actavis Group PTC ehf.
Proposed ATC code	R06A X27
Indication	Relief of symptoms associated with: - allergic rhinitis - urticaria
CHMP opinion date	17/11/2011
Marketing authorisation date	13/01/2012

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Invented name	Desloratadine ratiopharm
INN	desloratadine
Marketing Authorisation Holder	ratiopharm GmbH
Proposed ATC code	R06A X27
Indication	Relief of symptoms associated with: - allergic rhinitis - urticaria
CHMP opinion date	17/11/2011
Marketing authorisation date	13/01/2012

Invented name	Docetaxel Mylan
INN	docetaxel
Marketing Authorisation Holder	Mylan S.A.S.
Proposed ATC code	L01CD02
Indication	Breast cancer 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). 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. As 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. 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. 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.

Invented name	Docetaxel Mylan
	Non-small cell lung cancer Indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of prior chemotherapy. 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 In combination with prednisone or prednisolone is indicated for the treatment of patients with hormone refractory metastatic prostate cancer. Gastric adenocarcinoma 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 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.
CHMP opinion date	17/11/2011
Marketing authorisation date	31/01/2012