



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 May 2016
EMA/CHMP/337417/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Pemetrexed Fresenius Kabi

pemetrexed

On 26 May 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Pemetrexed Fresenius Kabi, intended for the treatment of unresectable malignant pleural mesothelioma and locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology. The applicant for this medicinal product is Fresenius Kabi Oncology Plc.

Pemetrexed Fresenius Kabi will be available as powder (100 mg and 500 mg) for concentrate for solution for infusion. The active substance of Pemetrexed Fresenius Kabi, pemetrexed, is a multi-targeted anti-cancer anti-folate agent (ATC code: L01BA04) that exerts its action by disrupting crucial folate dependent metabolic processes essential for cell replication.

Pemetrexed Fresenius Kabi is a generic of Alimta, which has been authorised in the EU since 20 September 2004. Studies have demonstrated the satisfactory quality of Pemetrexed Fresenius Kabi. Since Pemetrexed Fresenius Kabi is administered intravenously and is 100% bioavailable, a bioequivalence study versus the reference product Alimta was not required. A question and answer document on generic medicines can be found [here](#).

The full indication is:

"Malignant pleural mesothelioma

Pemetrexed Fresenius Kabi in combination with cisplatin is indicated for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma.

Non small cell lung cancer

Pemetrexed Fresenius Kabi in combination with cisplatin is indicated for the first line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology (see section 5.1).

Pemetrexed Fresenius Kabi is indicated as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose

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



disease has not progressed immediately following platinum-based chemotherapy (see section 5.1).

Pemetrexed Fresenius Kabi is indicated as monotherapy for the second line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology (see section 5.1)."

It is proposed that Pemetrexed Fresenius Kabi be subject to prescription and administered under the supervision of physicians experienced in the use of anti-cancer 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 made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.