EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 October 2022
EMA/CHMP/808787/2022
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Pemetrexed Baxter

pemetrexed

On 13 October 2022, 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 Baxter, intended for the treatment of malignant pleural mesothelioma and non-small cell lung cancer. The applicant for this medicinal product is Baxter Holding B.V.

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

Pemetrexed Baxter is a generic of Alimta, which has been authorised in the EU since 20 September 2004. Since Pemetrexed Baxter 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 Baxter in combination with cisplatin is indicated for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma.

Non-small cell lung cancer

Pemetrexed Baxter 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 Baxter 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 disease has not progressed immediately following platinum-based

[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

**Official address** Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
**Address for visits and deliveries** Refer to www.ema.europa.eu/how-to-find-us
**Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

chemotherapy (see section 5.1).

Pemetrexed Baxter 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 Baxter 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.