24 September 2015
EMA/CHMP/572488/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ciambra

pemetrexed

On 24 September 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ciambra, 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 Menarini International Operations Luxembourg S.A.

Ciambra will be available as 100 mg and 500 mg powder for concentrate for solution for infusion. The active substance of Ciambra, pemetrexed, is 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.

Ciambra is a generic of Alimta, which has been authorised in the EU since 20 September 2004. Studies have demonstrated the satisfactory quality of Ciambra. Since Ciambra 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

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

Non-small cell lung cancer

Ciambra 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).

Ciambra 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 chemotherapy (see section 5.1).

[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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

Ciambra 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 Ciambra 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.