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EPAR summary for the public

Ciambra

pemetrexed

This is a summary of the European public assessment report (EPAR) for Ciambra. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Ciambra.

For practical information about using Ciambra, patients should read the package leaflet or contact their doctor or pharmacist.

What is Ciambra and what is it used for?

Ciambra is a cancer medicine used to treat two types of lung cancer:

- malignant pleural mesothelioma (a cancer of the lining of the lungs that is usually caused by exposure to asbestos), where it is used together with cisplatin in patients who have not received chemotherapy before and whose cancer cannot be removed by surgery;
- advanced non-small-cell lung cancer of the kind known as 'non-squamous', where it is used either in combination with cisplatin in previously untreated patients or on its own in patients who have previously received cancer treatment. It can also be used as a maintenance treatment in patients who have received a platinum-based chemotherapy.

Ciambra is a 'generic medicine'. This means that Ciambra is similar to a 'reference medicine' already authorised in the European Union (EU) called Alimta. For more information on generic medicines, see the question-and-answer document here.

Ciambra contains the active substance pemetrexed.

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How is Ciambra used?

Ciambra is available as a powder that is made up into a solution for infusion (drip) into a vein. The medicine can only be obtained with a prescription and should only be given under the supervision of a doctor who is qualified in the use of chemotherapy.

The recommended dose is 500 mg per square metre of body surface area (calculated using the patient's height and weight). It is given once every three weeks as an infusion lasting 10 minutes. To reduce side effects, patients should take a corticosteroid (a type of medicine that reduces inflammation) and folic acid (a type of vitamin), and receive injections of vitamin B12 during treatment with Ciambra. When Ciambra is given with cisplatin, an 'anti-emetic' medicine (to prevent vomiting) and fluids (to prevent dehydration) should also be given before or after the cisplatin dose.

Treatment should be delayed or stopped, or the dose reduced, in patients whose blood counts are abnormal or who have certain other side effects. For more information, see the summary of product characteristics (also part of the EPAR).

How does Ciambra work?

The active substance in Ciambra, pemetrexed, is a cytotoxic medicine (a medicine that kills cells that are dividing, such as cancer cells), which belongs to the group 'antimetabolites'. In the body, pemetrexed is converted into an active form that blocks the activity of the enzymes that are involved in producing 'nucleotides' (the building blocks of DNA and RNA, the genetic material of cells). As a result, the active form of pemetrexed slows down the formation of DNA and RNA and prevents the cells from dividing and multiplying. The conversion of pemetrexed into its active form occurs more readily in cancer cells than in normal cells, leading to higher levels of the active form of the medicine and a longer duration of action in cancer cells. This results in the division of cancer cells being reduced, while normal cells are only slightly affected.

How has Ciambra been studied?

The company provided data from the published literature on pemetrexed. No additional studies were needed as Ciambra is a generic medicine that is given by infusion and contains the same active substance as the reference medicine, Alimta.

What are the benefits and risks of Ciambra?

Because Ciambra is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Ciambra approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Ciambra has been shown to be comparable to Alimta. Therefore, the CHMP's view was that, as for Alimta, the benefit outweighs the identified risk. The Committee recommended that Ciambra be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Ciambra?

A risk management plan has been developed to ensure that Ciambra is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and

the package leaflet for Ciambra, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Ciambra

The European Commission granted a marketing authorisation valid throughout the European Union for Ciambra on 2 December 2015.

The full EPAR and risk management plan summary for Ciambra can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Ciambra, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 12-2015