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EPAR summary for the public

Alimta

pemetrexed

This is a summary of the European public assessment report (EPAR) for Alimta. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Alimta.

What is Alimta?

Alimta is a powder that is made up into a solution for infusion (drip into a vein). It contains the active substance pemetrexed.

What is Alimta used for?

Alimta is 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 anticancer treatment. It can also be used as a maintenance treatment in patients who have received a platinum-based chemotherapy.

The medicine can only be obtained with a prescription.

How is Alimta used?

Alimta should only be given under the supervision of a doctor who is qualified in the use of chemotherapy.

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The recommended dose of Alimta 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 Alimta. When Alimta 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 Alimta work?

The active substance in Alimta, 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 Alimta been studied?

For the treatment of malignant pleural mesothelioma, Alimta in combination with cisplatin has been compared with cisplatin alone in one main study in 456 patients who had not received chemotherapy for their disease before.

For the treatment of locally advanced or metastatic non small cell lung cancer, Alimta was compared with gemcitabine (another anticancer medicine), in combination with cisplatin, in a study involving 1,725 patients who had not received chemotherapy before.

Alimta was also compared with docetaxel (another anticancer medicine) in one study involving 571 patients who had received chemotherapy in the past. For maintenance treatment, Alimta was compared with placebo (a dummy treatment) in two main studies involving 1,202 patients whose cancer had not got worse during platinum-based chemotherapy.

The main measures of effectiveness were how long the patients survived and how long they lived without their cancer getting worse.

What benefit has Alimta shown during the studies?

Alimta increased the survival time of patients with malignant pleural mesothelioma. Patients receiving Alimta and cisplatin survived for an average of 12.1 months, compared with 9.3 months in those receiving cisplatin alone.

In the treatment of non small cell lung cancer, Alimta was as effective as the comparators, with survival times around 10.3 months in patients who had not received chemotherapy in the past, and around 8.1 months in those who had received chemotherapy in the past.

In one maintenance treatment study, patients receiving Alimta lived for a further 4.3 months from the start of maintenance treatment without their cancer getting worse, compared with 2.6 months in those

receiving placebo. In the second maintenance study, the figures were 4.1 months in the Alimta and 2.8 months in the placebo group.

Improved survival times with Alimta were only seen in patients with non small cell lung cancer of the non-squamous type.

What is the risk associated with Alimta?

The most common side effects with Alimta, used on its own or with other anticancer medicines, are bone marrow suppression (when the bone marrow produces less blood cells than normal) and gastrointestinal toxicities (side effects affecting the stomach and gut). Bone marrow suppression causes decreased levels in the blood of white blood cells (the cells that fight infection), platelets (components that help the blood to clot) and haemoglobin (the protein found in red blood cells that carries oxygen around the body). The gastrointestinal toxicities seen with Alimta are loss of appetite, nausea (feeling sick), vomiting, diarrhoea, constipation, pharyngitis (sore throat), and mucositis or stomatitis (inflammation of the lining of the digestive system and mouth). For the full list of all side effects reported with Alimta, see the package leaflet.

Alimta must not be used in people who are hypersensitive (allergic) to pemetrexed or any of the other ingredients. It must not be used during breast-feeding or at the same time as the vaccine for yellow fever. Alimta affects fertility, so both men and women who receive it need to be made aware of this.

Why has Alimta been approved?

The CHMP concluded that Alimta's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Alimta

The European Commission granted a marketing authorisation valid throughout the European Union for Alimta on 20 September 2004.

The full EPAR for Alimta 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 Alimta, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2011.