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EPAR summary for the public

Pemetrexed Hospira UK Limited

pemetrexed

This is a summary of the European public assessment report (EPAR) for Pemetrexed Hospira UK Limited. 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 Pemetrexed Hospira UK Limited.

For practical information about using Pemetrexed Hospira UK Limited, patients should read the package leaflet or contact their doctor or pharmacist.

What is Pemetrexed Hospira UK Limited and what is it used for?

Pemetrexed Hospira UK Limited 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 platinum-based chemotherapy.

Pemetrexed Hospira UK Limited contains the active substance pemetrexed. It is a 'generic medicine'. This means that Pemetrexed Hospira UK Limited contains the same active substance and works in the same way as 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.

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How is Pemetrexed Hospira UK Limited used?

Pemetrexed Hospira UK Limited 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 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 Pemetrexed Hospira UK Limited. When Pemetrexed Hospira UK Limited 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 Pemetrexed Hospira UK Limited work?

The active substance in Pemetrexed Hospira UK Limited 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 Pemetrexed Hospira UK Limited been studied?

Studies on the benefits and risks of the active substance in the approved uses have already been carried out with the reference medicine, Alimta, and do not need to be repeated for Pemetrexed Hospira UK Limited.

As for every medicine, the company provided studies on the quality of Pemetrexed Hospira UK Limited. There was no need for 'bioequivalence' studies to investigate whether Pemetrexed Hospira UK Limited is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Pemetrexed Hospira UK Limited is given by infusion into a vein, so the active substance is delivered straight into the bloodstream.

What are the benefits and risks of Pemetrexed Hospira UK Limited?

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

Why is Pemetrexed Hospira UK Limited approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Pemetrexed Hospira UK Limited 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 Pemetrexed Hospira UK Limited be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Pemetrexed Hospira UK Limited?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Pemetrexed Hospira UK Limited have been included in the summary of product characteristics and the package leaflet.

Other information about Pemetrexed Hospira UK Limited

The European Commission granted a marketing authorisation valid throughout the European Union for Pemetrexed Hospira UK Limited on 24 April 2017.

The full EPAR for Pemetrexed Hospira UK Limited 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 Pemetrexed Hospira UK Limited, 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 04/2017.