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Pemetrexed Baxter (*pemetrexed*)

An overview of Pemetrexed Baxter and why it is authorised in the EU

What is Pemetrexed Baxter and what is it used for?

Pemetrexed Baxter 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 or metastatic (meaning it has spread to other parts of the body) '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.

Pemetrexed Baxter is a 'generic medicine'. This means that Pemetrexed Baxter contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Alimta. For more information on generic medicines, see the question-and-answer document here.

Pemetrexed Baxter contains the active substance pemetrexed.

How is Pemetrexed Baxter used?

Pemetrexed Baxter 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.

Pemetrexed Baxter is given once every three weeks as an infusion (drip) into a vein 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 Baxter.

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 about using Pemetrexed Baxter, see the package leaflet or contact your doctor or pharmacist.

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How does Pemetrexed Baxter work?

The active substance in Pemetrexed Baxter, pemetrexed, is a cytotoxic medicine (a medicine that kills cells that are dividing, such as cancer cells). 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). 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 Baxter been studied?

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

As for every medicine, the company provided studies on the quality of Pemetrexed Baxter. There was no need for 'bioequivalence' studies to investigate whether Pemetrexed Baxter is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Pemetrexed Baxter 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 Baxter?

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

Why is Pemetrexed Baxter authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Pemetrexed Baxter has been shown to have comparable quality and to be bioequivalent to Alimta. Therefore, the Agency's view was that, as for Alimta, the benefits of Pemetrexed Baxter outweigh the identified risks and it can be authorised for use in the EU.

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

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

As for all medicines, data on the use of Pemetrexed Baxter are continuously monitored. Suspected side effects reported with Pemetrexed Baxter are carefully evaluated and any necessary action taken to protect patients.

Other information about Pemetrexed Baxter

Pemetrexed Baxter received a marketing authorisation valid throughout the EU on 09 December 2022.

Further information on Pemetrexed Baxter can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/pemetrexed-baxter. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 12-2022.