



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Pemetrexed Pfizer<sup>1</sup> (*pemetrexed*)

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

### What is Pemetrexed Pfizer and what is it used for?

Pemetrexed Pfizer 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.

Pemetrexed Pfizer contains the active substance pemetrexed and is a 'generic medicine'. This means that Pemetrexed Pfizer contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Pemetrexed Pfizer is Alimta. For more information on generic medicines, see the question-and-answer document [here](#).

### How is Pemetrexed Pfizer used?

Pemetrexed Pfizer 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. It is given as an infusion (drip) into a vein, once every three weeks. The recommended dose depends on the patient's height and weight.

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 Pfizer. When Pemetrexed Pfizer 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.

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<sup>1</sup> Previously known as Pemetrexed Hospira



For more information about using Pemetrexed Pfizer, see package leaflet or contact your doctor or pharmacist .

## **How does Pemetrexed Pfizer work?**

The active substance in Pemetrexed Pfizer, 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 Pemetrexed Pfizer 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 Pfizer.

The company provided data from the published literature on pemetrexed. There was no need for 'bioequivalence' studies to investigate whether Pemetrexed Pfizer is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Pemetrexed Pfizer 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 Pfizer?**

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

## **Why is Pemetrexed Pfizer authorised in the EU?**

The European Medicines Agency concluded that, in accordance with EU requirements, Pemetrexed Pfizer has been shown to be comparable to Alimta. Therefore, the Agency's view was that, as for Alimta, the benefits of Pemetrexed Pfizer 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 Pfizer?**

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Pemetrexed Pfizer have been included in the summary of product characteristics and the package leaflet. Any additional measures in place for Alimta also apply to Pemetrexed Pfizer where appropriate.

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

## **Other information about Pemetrexed Pfizer**

Pemetrexed Hospira received a marketing authorisation valid throughout the EU on 20 November 2015.

The name of the medicine was changed to Pemetrexed Pfizer on 29 August 2022.

Further information on Pemetrexed Pfizer can be found on the Agency's website: [ema.europa.eu/medicines/human/EPAR/pemetrexed-pfizer](https://ema.europa.eu/medicines/human/EPAR/pemetrexed-pfizer). Information on the reference medicine can also be found on the Agency's website.

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