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Pemetrexed Krka (*pemetrexed*)

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

What is Pemetrexed Krka and what is it used for?

Pemetrexed Krka 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 Krka contains the active substance pemetrexed. It is a 'generic medicine'. This means that Pemetrexed Krka 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.

How is Permetrexed Krka used?

Pemetrexed Krka 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 of Permetrexed Krka 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 B_{12} during treatment with Pemetrexed Krka. When Pemetrexed Krka is given with cisplatin, an antiemetic medicine (to prevent vomiting) and fluids (to prevent dehydration) should also be given before or after the cisplatin dose.

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

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

How does Pemetrexed Krka work?

The active substance in Pemetrexed Krka, 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 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. Pemetrexed is converted into its active form 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 slows down the division of cancer cells, while normal cells are only slightly affected.

How has Pemetrexed Krka 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 Krka.

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

Because Pemetrexed Krka 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 Krka authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Pemetrexed Krka has been shown to be comparable to Alimta. Therefore, the Agency's view was that, as for Alimta, the benefit of Pemetrexed Krka outweighs the identified risk and it can be authorised for use in the EU.

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

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

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

Other information about Pemetrexed Krka

Pemetrexed Krka received a marketing authorisation valid throughout the EU on 22 May 2018.

Further information on Pemetrexed Krka can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 05-2018.