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EPAR summary for the public

Armisarte[1]

pemetrexed

This is a summary of the European public assessment report (EPAR) for Armisarte. 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 Armisarte.

For practical information about using Armisarte, patients should read the package leaflet or contact their doctor or pharmacist.

What is Armisarte and what is it used for?

Armisarte 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.

Armisarte is a 'hybrid medicine'. This means that Armisarte is similar to a 'reference medicine' already authorised in the European Union (EU) called Alimta, but it is available in a different form. While Alimta is available as a powder to be made up into a solution for infusion (drip) into a vein, Armisarte is available as a concentrated liquid to be made up into a solution for infusion.

Armisarte contains the active substance pemetrexed.

[1] [1]Previously known as Pemetrexed Actavis.

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How is Armisarte used?

Armisarte is available as a concentrate for solution for infusion 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 cancer medicines.

The recommended dose 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 Armisarte. When Armisarte 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 Armisarte work?

The active substance in Armisarte, 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 Armisarte been studied?

The company provided data from the published literature on pemetrexed. No additional studies were needed as Armisarte is a hybrid medicine that is given by infusion and contains the same active substance as the reference medicine, Alimta.

What are the benefits and risks of Armisarte?

Because Armisarte is a hybrid medicine that is given by infusion and contains the same active substance as the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Armisarte approved?

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

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

A risk management plan has been developed to ensure that Armisarte is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Armisarte, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Armisarte

The European Commission granted a marketing authorisation valid throughout the European Union for Pemetrexed Actavis on 18 January 2016. The name of the medicine was changed to Armisarte on 10 February 2016.

The full EPAR and risk management plan summary for Armisarte 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 Armisarte, 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 02-2016.