Summary Public Assessment Report

Generics

Pemetrexed Synthon 100 mg, 500 mg and 1000 mg, powder for concentrate for solution for infusion

(pemetrexed)

NL/H/3325/001-003/DC

Date: 13 July 2016

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Active substance: pemetrexed

This is a summary of the public assessment report (PAR) for Pemetrexed Synthon. It explains how this medicine was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Pemetrexed Synthon.

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

What is Pemetrexed Synthon and what is it used for?
Pemetrexed Synthon is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Alimta.

Pemetrexed Synthon 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 '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 anticancer treatment. It can also be used as a maintenance treatment in patients who have received a platinum-based chemotherapy.

How does this medicine work?
The active substance in 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 is this medicine used?
Pemetrexed Synthon is a powder that is made up into a solution for infusion (drip into a vein). The medicine can only be obtained with a prescription.

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 this medicine. When Pemetrexed Synthon 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.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

How has this medicine been studied?
No additional studies were needed as Pemetrexed Synthon is a generic medicine that is given by infusion and contains the same active substance as the reference medicine, Alimta.

What are the possible side effects of this medicine?
Because Pemetrexed Synthon is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.
For the full list of all side effects reported with this medicine, see section 4 of the package leaflet.

Why is this medicine approved?
It was concluded that, in accordance with EU requirements, this medicine has been shown to have comparable quality to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for Alimta, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of this medicine?
A risk management plan has been developed to ensure that this medicine 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 Pemetrexed Synthon, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about this medicine
In the Netherlands, the marketing authorisation for Pemetrexed Synthon 100 mg, 500 mg and 1000 mg, powder for concentrate for solution for infusion was granted on 14 December 2015.

The full PAR for this medicine can be found on the website http://mri.medagencies.org/Human. For more information about treatment with Pemetrexed Synthon, read the package leaflet (http://mri.medagencies.org/Human/Product/Details/45682) or contact your doctor or pharmacist.

This summary was last updated in July 2016.