LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Pemetrexed Pharmaswiss (pemetrexed)

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Summary Public Assessment Report

Pemetrexed Pharmaswiss

(pemetrexed)

Powder for concentrate for solution for infusion, 100 mg and 500mg

This is a summary of the public assessment report (PAR) for Pemetrexed Pharmaswiss. It explains how Pemetrexed Pharmaswiss 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 Pharmaswiss.

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

What is Pemetrexed Pharmaswiss and what is it used for?

Pemetrexed Pharmaswiss is a 'generic medicine'. This means that Pemetrexed Pharmaswiss is similar to a 'reference medicine' already authorised in the European Union (EU) called Alimta.

Pemetrexed PharmaSwiss is a medicine used in the treatment of cancer.

Pemetrexed PharmaSwiss is given in combination with cisplatin, another anti-cancer medicine, as treatment for malignant pleural mesothelioma, a form of cancer that affects the lining of the lung, to patients who have not received prior chemotherapy.
Pemetrexed PharmaSwiss is also given in combination with cisplatin for the initial treatment of patients with advanced stage of lung cancer.

Pemetrexed PharmaSwiss can be prescribed to you if you have lung cancer at an advanced stage if your disease has responded to treatment or it remains largely unchanged after initial chemotherapy.
Pemetrexed PharmaSwiss is also a treatment for patients with advanced stage of lung cancer whose disease has progressed after other initial chemotherapy has been used.

How does Pemetrexed Pharmaswiss work?

The active substance in Pemetrexed Phamraswiss, 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 Pemetrexed Pharmaswiss used?
The pharmaceutical form of Pemetrexed Pharmaswiss is powder for concentrate for solution for infusion, for intravenous infusion.

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

The medicine can only be obtained with a prescription.

What benefits of Pemetrexed Pharmaswiss have been shown in studies?
No additional studies were needed as Pemetrexed Pharmaswiss is a generic medicine that is given by intravenous infusion and contains the same active substance as the reference medicine, Alimta.

What are the possible side effects of Pemetrexed Pharmaswiss?
Because Pemetrexed Pharmaswiss 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 restrictions, see the package leaflet.

Why is Pemetrexed Pharmaswiss approved?
It was concluded that, in accordance with EU requirements, Pemetrexed Pharmaswiss has been shown to have comparable quality and to be similar to the reference medicine Alimta. Therefore, the Medical Products Agency in Sweden decided that, as for Alimta, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Pemetrexed Pharmaswiss?
A risk management plan has been developed to ensure that Pemetrexed Pharmaswiss 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 Pharmaswiss, 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 Pemetrexed Pharmaswiss
The marketing authorisation for Pemetrexed Pharmaswiss was granted on 2016-04-07 in Sweden.

The full PAR for Pemetrexed Pharmaswiss can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Pemetrexed Pharmaswiss, please read the [package leaflet] or contact your doctor or pharmacist.

This summary was last updated in 2016-04.