LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Pemetrexed Sigillata
(pemetrexed)

SE/H/1491/01-03/DC

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Pemetrexed Sigillata

(pemetrexed)

Powder for concentrate for solution for infusion; 100 mg, 500 mg and 1000 mg

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

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

What is Pemetrexed Sigillata and what is it used for?

Pemetrexed Sigillata is similar to a 'reference medicine' already authorised in the European Union (EU) called ALIMTA.

Pemetrexed Sigillata is a medicine used in the treatment of cancer. It contains the active substance pemetrexed.

Pemetrexed Sigillata 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 Sigillata is also given in combination with cisplatin for the initial treatment of patients with advanced stage of lung cancer.

Pemetrexed Sigillata 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 Sigillata 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 Sigillata work?

Pemetrexed belongs to a group of medicines known as folic acid analogues and disrupts processes that are essential for cell replication.

How is Pemetrexed Sigillata used?

The pharmaceutical form of Pemetrexed Sigillata is powder for concentrate for solution for infusion into one of your veins.

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 Sigillata have been shown in studies?

No additional studies were needed as Pemetrexed Sigillata is a generic/hybrid medicine that is given by infusion and contains the same active substance as the reference medicine, ALIMTA.

What are the possible side effects of Pemetrexed Sigillata?

For the full list of all side effects reported with Pemetrexed Sigillata, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Pemetrexed Sigillata approved?

It was concluded that, in accordance with EU requirements, Pemetrexed Sigillata 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 Sigillata?

A risk management plan has been developed to ensure that Pemetrexed Sigillata 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 Sigillata, 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 Sigillata

The marketing authorisation for Pemetrexed Sigillata was granted on 2016-08-18 in Sweden.

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

This summary was last updated in 2016-10.