LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Metotrexat Accord (methotrexate)

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Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelverket.se E-mail: registrator@mpa.se

Summary Public Assessment Report

Metotrexat Accord
(methotrexate)

Concentrate for solution for infusion; 100 mg/ml

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

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

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

Metotrexat Accord is used in the treatment of the following types of cancer:
- acute lymphocytic leukaemia,
- non-Hodgkin's lymphomas,
- osteogenic sarcoma,
- adjuvant and in advance disease of breast cancer,
- metastatic or recurrent head and neck cancer,
- choriocarcinoma and similar trophoblastic diseases,
- advanced cancer of urinary bladder.

How does Metotrexat Accord work?
Methotrexate is a cytostatic that inhibits cell growth. Methotrexate has its greatest effect on cells which increase frequently like cancer cells, bone marrow cells and skin cells.

How is Metotrexat Accord used?
Metotrexat Accord is given to you by healthcare professionals.

The pharmaceutical form of Metotrexat Accord is concentrate for solution for infusion which can be given in muscle (intramuscularly), in a vein (intravenously), or in an artery (intra-arterially).

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 Metotrexat Accord have been shown in studies?
No additional studies were needed as Metotrexat Accord is a generic medicine that is given by infusion/intravenous injection and contains the same active substance as the reference medicine, Methotrexate Pfizer.

What are the possible side effects of Metotrexat Accord?
Because Metotrexat Accord 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 Metotrexat Accord approved?
It was concluded that, in accordance with EU requirements, Metotrexat Accord has been shown to have comparable quality and to be similar to the reference medicine Methotrexate Pfizer. Therefore, the Medical Products Agency in Sweden decided that, as for Methotrexate Pfizer, 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 Metotrexat Accord?
A risk management plan has been developed to ensure that Metotrexat Accord 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 Metotrexat Accord, 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 Metotrexat Accord
The marketing authorisation for Metotrexat Accord was granted on 2014-10-03 in Sweden.

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

This summary was last updated in 2014-10.