LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Methotrexate Afortas (methotrexate)

SE/H/2473/01/DC

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Summary Public Assessment Report

Methotrexate Afortas
methotrexate

Tablet, 2,5 mg

This is a summary of the public assessment report (PAR) for Methotrexate Afortas. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Methotrexate Afortas and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Methotrexate Pfizer.

Methotrexate Afortas is used in patients with:
- the following rheumatic and skin diseases:
  - active rheumatoid arthritis (RA) in adults
  - polyarthritic forms (when five or more joints are affected) of active, severe juvenile idiopathic arthritis (JIA) in adolescents and children aged 3 years and over when the response to non-steroidal anti-inflammatory drugs (NSAIDs) has been inadequate
  - severe, treatment-resistant, disabling psoriasis that does not respond sufficiently to other forms of treatment such as phototherapy, psoralen and ultraviolet A radiation (PUVA) therapy and retinoids, as well as in severe psoriasis that also affects the joints (psoriatic arthritis) in adult patients
- acute lymphoblastic leukaemia (ALL) in adults, adolescents and children aged 3 years and over

How does Methotrexate Afortas work?

Methotrexate Afortas is a medicine that:
- suppresses the growth of certain cells in the body that multiply rapidly (an anticancer medicine)
- reduces unwanted reactions by the body's own defence mechanisms (an immunosuppressive agent)
- has an anti-inflammatory effect

How is Methotrexate Afortas used?

The pharmaceutical form is tablets for oral use.

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 in Sweden.

What benefits of Methotrexate Afortas have been shown in studies?

Because the product is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Methotrexate Pfizer. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Methotrexate Afortas?

Because the product 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 side effects, see section 4 of the package leaflet.

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

Why is Methotrexate Afortas approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Methotrexate Pfizer, the benefits are greater than its risks and recommended that it can be approved for use.

The product has been authorised with the condition to perform further studies and/or to provide additional measures to minimise the risk. See section below "What measures are being taken to ensure the safe and effective use of Methotrexate Afortas?"

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

A risk management plan has been developed to ensure that the product 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, 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.

- **Additional risk minimisation measures (including educational material)**
  Prior to launch of the product in each Member State, the Marketing Authorisation Holder (MAH) must agree about the content and format of the educational materials, including communication media, distribution modalities, and any other aspects of the programme, with the National Competent Authority.
  The MAH shall ensure that, in each Member State where the product is marketed, all healthcare professionals who are expected to prescribe or dispense the product have access to the following educational package:
  • The Summary of Product Characteristics
  • The patient leaflet
  • Guide for healthcare professionals
  • Patient Card

  The full PAR for Methotrexate Afortas can be found on the following website: https://mri.cts-mrp.eu/portal/home?domain=h.

- **Obligation to conduct post-authorisation measures in accordance with Article 21a of Directive 2001/83/EC**

The MAH shall complete, within the stated timeframe, the below measures:

Description	Due date
The MAH should implement a targeted follow-up questionnaires for all medication errors resulting in overdose.	From the date of notification

	of the Commission Decision*

*Referral EMEA/H/A-31/1463

Other information about Methotrexate Afortas

The full PAR for Methotrexate Afortas can be found on the following website: https://mri.cts-mrp.eu/portal/home?domain=h. For more information about treatment with Methotrexate Afortas, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-02.