LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Methotrexate Sandoz
methotrexate

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Solution for injection in pre-filled injector, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 22.5 mg, 25mg, 27.5 mg and 30 mg.

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

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

What is Methotrexate Sandoz and what is it used for?

Methotrexate Sandoz is a 'generic medicine'. This means that Methotrexate Sandoz is similar to a 'reference medicine' already authorised in the European Union (EU) called Metoject.

Methotrexate Sandoz modifies and slows down the progression of the disease. Methotrexate Sandoz is used in the treatment of the following diseases:

- Rheumatoid arthritis (RA) in adult patients. RA is a chronic disease, characterised by inflammation of the joint membranes. These membranes produce a fluid which acts as a lubricant for many joints. The inflammation causes thickening of the membrane and swelling of the joint.

- Polyarthritic forms of severe active juvenile idiopathic arthritis when treatment with nonsteroidal anti-inflammatory drugs (NSAIDs) have not helped. (Juvenile arthritis concerns children and adolescents less than 16 years.)

- Severe Psoriatic arthritis in adult patients (psoriatic arthritis is a kind of arthritis with psoriatric lesions of the skin and nails, especially at the joints of fingers and toes.)

- Severe Psoriasis which has not responded to other forms of treatment (psoriasis is a common chronic skin disease, characterised by red patches covered by thick, dry, silvery, adherent scales.)

- Crohn's Disease in adult patients (Crohn's Disease is a type of inflammatory bowel disease causing symptoms such as abdominal pain, diarrhoea, vomiting or weight loss.)

How does Methotrexate Sandoz work?

Methotrexate is a substance with following properties:

- it interferes with the growth of certain cells in the body that reproduce quickly
- it reduces the activity of the immune system (the body's own defence mechanism)
- it has anti-inflammatory effects

How is Methotrexate Sandoz used?

The pharmaceutical form of Methotrexate Sandoz is Solution for injection in pre-filled injector for subcutaneous 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 Sandoz have been shown in studies?

No additional studies were needed as Methotrexate Sandoz is a generic medicine that is given by subcutaneous injection and contains the same active substance as the reference medicine, Metoject.

What are the possible side effects of Methotrexate Sandoz?

Because Methotrexate Sandoz 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 Methotrexate Sandoz approved?

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

Methotrexate Sandoz 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 Sandoz?”

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

A risk management plan has been developed to ensure that Methotrexate Sandoz 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 Methotrexate Sandoz, 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.

As for all methotrexate-containing products, the company also needs to implement a specific adverse reaction follow-up questionnaire. This is to discover and characterize the risk for medical errors that may result in overdose.

Other information about Methotrexate Sandoz

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

This summary was last updated in 2021-05.