LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Metoject
(methotrexate)

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Summary Public Assessment Report

Metoject
(methotrexate)

Solution for injection in pre-filled pen, 7,5 mg, 10mg, 15mg, 20mg, 25mg

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

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

What is Metoject and what is it used for?

Metoject is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but is available as solution for injection in pre-filled pen.

The reference medicine for Metoject is also called Metoject. Metoject is indicated for the treatment of

- active rheumatoid arthritis in adult patients.
- severe recalcitrant disabling psoriasis, which is not adequately responsive to other forms of therapy such as phototherapy, PUVA, and retinoids, and severe psoriatic arthritis in adult patients.

How does Metoject work?

Methotrexate is a folic acid antagonist which belongs to the class of cytotoxic agents known as antimetabolites. Metoject modifies and slows down the progression of the above mentioned diseases.

How is Metoject used?

The pharmaceutical form of Metoject is Solution for injection in pre-filled pen 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.

What benefits of Metoject have been shown in studies?

Because Metoject is a hybrid application and is considered to be therapeutically equivalent, to the reference product Metoject, their benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects of Metoject?

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

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

Why is Metoject approved?

This medicine is similar to a reference medicine containing the same active substance, but is available *as* solution for injection in pre-filled pen.

The company has provided additional own data to demonstrate the safety and efficacy of Metoject regarding this difference from the reference medicine.
No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Metoject's benefits are greater than its risks and recommended that it be approved for use.

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

A risk management plan has been developed to ensure that Metoject 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 Metoject, 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 Metoject

The marketing authorisation for Metoject was granted on 2018-01-30 in Sweden.

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

This summary was last updated in 2018-01.