

Summary Public Assessment Report

Metotab (methotrexate disodium)

SE/H/2110/01-03/MR

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Metotab
methotrexate disodium

Tablet, 7,5 mg, 2,5 mg, 10 mg

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

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

What is Metotab and what is it used for?

Metotab is a medicine with 'well-established use'. This means that the medicinal use of the active substance of Metotab is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

Metotab is used in the treatment of

- severe, active rheumatoid arthritis in adult patients.
- severe and generalised psoriasis vulgaris, especially of the plaque type, in adult patients.

Rheumatoid arthritis (RA) is a chronic autoimmune disease, characterised by joint inflammation, leading to swelling of joints, difficulties in moving and pain.

Psoriasis vulgaris is a chronic autoimmune disease of the skin, characterised by patches of red, thickened, dry skin, often covered by silvery scales.

How does Metotab work?

Metotab affects and slows down the course of the disease.

How is Metotab used?

The pharmaceutical form of Metotab is tablet 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 Metotab have been shown in studies?

As methotrexate is a well-known substance, and its use in the treatment of severe, active rheumatoid arthritis and severe and generalised psoriasis vulgaris, especially of the plaque type, in adult patients, is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of methotrexate in the treatment of severe, active rheumatoid arthritis and severe and generalised psoriasis vulgaris, especially of the plaque type, in adult patients.

What are the possible side effects from Metotab?

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 Metotab approved?

The Swedish Medical Products Agency decided that Metotab's 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 Metotab?

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

The full PAR for Metotab can be found on the following website: <http://mri.medagencies.org/Human/> for more information about treatment with Metotab.

This summary was last updated in 2021-11.