

Summary Public Assessment Report

Metotrexat Astron (methotrexate)

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(methotrexate)

Solution for injection in prefilled syringe; 50 mg/ml

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

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

What is Metotrexat Astron and what is it used for?

Metotrexat Astron is a ‘hybrid medicine’. This means that it is similar to a reference medicine containing the same active substance, but is available in a different strength.

The reference medicine for Metotrexat Astron is Metoject.

Metotrexat Astron is indicated for the treatment of

- active rheumatoid arthritis in adult patients.
- polyarthritic forms of severe, active juvenile idiopathic arthritis, when the response to nonsteroidal anti-inflammatory drugs (NSAIDs) has been inadequate,
- 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.
- mild to moderate Crohn’s Disease in adult patients when adequate treatment with other medicines is not possible.

How does Metotrexat Astron 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 Metotrexat Astron used?

The pharmaceutical form of Metotrexat Astron is solution for injection in prefilled syringe for subcutaneous administration (under the skin).

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 Astron have been shown in studies?

Because Metotrexat Astron 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 Metotrexat Astron?

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

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

Why is Metotrexat Astron approved?

This medicine is similar to a reference medicine containing the same active substance, but is available in a different strength. No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Metotrexat Astron'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 Metotrexat Astron?

A risk management plan has been developed to ensure that Metotrexat Astron 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 Astron, 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 Astron

The marketing authorisation for Metotrexat Astron was granted on 2015-11-26 in Sweden.

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

This summary was last updated in 2015-12.