LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Namaxir
(methotrexate disodium)

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Summary Public Assessment Report

Namaxir

(methotrexate disodium)

Solution for injection, pre-filled syringe, 2.5 mg, 7.5 mg, 10 mg, 12.5 mg, 15mg, 17.5 mg, 20 mg, 22.5 mg, 25 mg, 27.5 mg, 30 mg

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

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

What is Namaxir and what is it used for?

Namaxir is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but consists of different concentrations of methotrexate and lower volumes for injection compared to the reference product Metoject 10mg/ml.

The reference medicine for Namaxir is Metoject 10 mg/ml Solution for Injection, Pre-filled Syringe, authorized in Sweden since 2002.

Namaxir is used in 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 either alone or in combination with corticosteroids in adult patients refractory or intolerant to thiopurines.

How does Namaxir work?

Methotrexate is a substance with the 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 Namaxir used?

The pharmaceutical form of Namaxir is solution for injection in pre-filled syringe for administration as an injection.

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 Namaxir have been shown in studies?

Because Namaxir is a hybrid application and is considered to be therapeutically equivalent to the reference product Metoject 10 mg/ml Solution for Injection, Pre-filled Syringe, their benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects of Namaxir?

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

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

Why is Namaxir approved?

This medicine is similar to a reference medicine containing the same active substance, but consists of different concentrations of methotrexate and lower volumes for injection compared to the reference product Metoject 10mg/ml.

No new studies on pharmacodynamics, clinical efficacy or clinical safety have been submitted. As methotrexate is a widely used, well-known active substance, no data are required for an abridged application provided bioequivalence has been satisfactorily demonstrated. The Clinical Overview is based on literature review and is considered appropriate.

No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Namaxir'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 Namaxir?

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

The marketing authorisation for Namaxir was granted on 2015-11-12 in Sweden.

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

This summary was last updated in 2015-11-12.