LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Injexate
(methotrexate)

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Summary Public Assessment Report

Injexate

(methotrexate)

Solution for injection in prefilled syringe; 50 mg/ml

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

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

What is Injexate and what is it used for?

Injexate 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 Injexate is Metoject.

Injexate 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 Injexate 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 Injexate used?

The pharmaceutical form of Injexate 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 Injexate have been shown in studies?

Because Injexate 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 Injexate?

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

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

Why is Injexate 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 Injexate'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 Injexate?

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

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

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

This summary was last updated in 2015-12.