LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Injexate
(methotrexate)

SE/H/1431/02-11/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@mpa.se

Summary Public Assessment Report

Injexate

(methotrexate)

Solution for injection in pre-filled injector, 7,5mg, 10mg, 12,5mg, 15mg, 17,5mg, 20mg, 22,5mg, 25mg, 27,5mg, 30mg

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 as solution for injection in pre-filled injector.

The reference medicine for Injexate is Metoject.

Injexate is indicated for the treatment of:

- Rheumatoid arthritis (RA) in adult patients- (RA) is a chronic disease, characterised by inflammation of the joint membranes. These membranes produce a fluid which acts as a lubricant for many joints. The inflammation causes thickening of the membrane and swelling of the joint.

- Polyarthritic forms of severe active juvenile idiopathic arthritis when treatment with nonsteroidal anti-inflammatory drugs (NSAIDs) have not helped. (Juvenile arthritis concerns children and adolescents less than 16 years.)

- Severe Psoriatic arthritis in adult patients (psoriatic arthritis is a kind of arthritis with psoriatric lesions of the skin and nails, especially at the joints of fingers and toes.)

- Severe Psoriasis which has not responded to other forms of treatment (psoriasis is a common chronic skin disease, characterised by red patches covered by thick, dry, silvery, adherent scales.)

- Crohn's Disease in adult patients (Crohn's Disease is a type of inflammatory bowel disease causing symptoms such as abdominal pain, diarrhoea, vomiting or weight loss.)

Injexate modifies and slows down the progression of the disease.

How does Injexate work?

Injexate contains methotrexate as active substance. 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 pre-filled injector 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 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 as solution for injection in pre-filled injector. The company has provided additional own data to demonstrate the safety and efficacy of Injexate 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 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 2017-05-03 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 2017-05.