

Summary Public Assessment Report

Methotrexate Orion (methotrexate)

SE/H/1422/01/DC

Summary Public Assessment Report

Methotrexate Orion
(methotrexate)

Solution for injection in pre-filled syringe, 25 mg/ml

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

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

What is Methotrexate Orion and what is it used for?

Methotrexate Orion is a 'generic medicine'. This means that Methotrexate Orion is similar to a 'reference medicine' already authorised in the European Union (EU) called Lantarel FS.

Methotrexate Orion is used for the treatment of:

- active rheumatoid arthritis (RA) in adult patients
- polyarthritic forms (when five or more joints are involved) of severe, active juvenile idiopathic arthritis (JIA) when the response to non-steroidal 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 psoriasis arthritis(affecting the joints) in adult patients.

How does Methotrexate Orion 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

Methotrexate Orion modifies and slows down the progression of the disease.

How is Methotrexate Orion used?

The pharmaceutical form of Methotrexate Orion is a solution for injection pre-filled syringe that may be injected intramuscularly (in a muscle) or subcutaneously (under the skin). Methotrexate Orion is administered by or under the supervision of a physician or healthcare staff 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 Methotrexate Orion have been shown in studies?

No additional studies were needed as Methotrexate Orion is a generic medicine that is given by injection and contains the same active substance as the reference medicine, Lantarel FS.

What are the possible side effects of Methotrexate Orion?

Because Methotrexate Orion is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Methotrexate Orion approved?

It was concluded that, in accordance with EU requirements, Methotrexate Orion has been shown to have comparable quality and to be similar to the reference medicine Lantarel FS. Therefore, the Medical Products Agency in Sweden decided that, as for Lantarel FS, the 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 Methotrexate Orion?

A risk management plan has been developed to ensure that Methotrexate Orion 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 Methotrexate Orion, 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 Methotrexate Orion

The marketing authorisation for Methotrexate Orion was granted on 2015-04-16 in Sweden.

The full PAR for Methotrexate Orion can be found on the following website:

<http://mri.medagencies.org/Human/>. For more information about treatment with Methotrexate Orion, please read the [\[package leaflet\]](#) or contact your doctor or pharmacist.

This summary was last updated in 2015-04.