

Summary Public Assessment Report

Methotrexate Orion Pharma methotrexate

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Methotrexate Orion Pharma
(methotrexate)
Tablet, 2.5 mg and 10 mg

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

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

What is Methotrexate Orion Pharma and what is it used for?

Methotrexate Orion Pharma 2.5 mg is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Methotrexate Pfizer.

Methotrexate Orion Pharma 10 mg is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but in another strength. The company has provided additional own data to demonstrate the safety and efficacy of Methotrexate Orion Pharma regarding this difference from the reference medicine. The reference medicine for Methotrexate Orion Pharma is Methotrexate Pfizer.

Methotrexate Orion Pharma is used in the treatment of

- active rheumatoid arthritis in adult patients
- severe recalcitrant disabling psoriasis, which is not adequately responsive to other forms of therapy such as phototherapy, PUVA and retinoids
- severe psoriatic arthritis in adult patients
- maintenance therapy in acute lymphoblastic leukaemia

How does Methotrexate Orion Pharma work?

The active substance of Methotrexate Orion Pharma tablets, methotrexate, is a substance with the following properties:

- it interferes with the growth of certain cells in the body that reproduce quickly and hence slows down the growth of tumour cells
- it reduces the activity of the immune system (the body's own defence mechanism)
- it has anti-inflammatory effects.

How is Methotrexate Orion Pharma used?

The pharmaceutical form of Methotrexate Orion Pharma is tablet for oral 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 Methotrexate Orion Pharma have been shown in studies?

Methotrexate Orion Pharma 2.5 mg tablet is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Methotrexate Pfizer 2.5 mg tablet. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

Because Methotrexate Orion Pharma 10 mg tablet is a hybrid application of Methotrexate Pfizer 2.5 mg, clinical studies have been provided for Methotrexate Orion Pharma to show efficacy for the difference of Methotrexate Orion Pharma from the reference product Methotrexate Pfizer 2.5 mg tablet.

What are the possible side effects of Methotrexate Orion Pharma?

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

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

Why is Methotrexate Orion Pharma approved?

It was concluded that, in accordance with EU requirements, Methotrexate Orion Pharma 2.5 mg has been shown to have comparable quality and to be similar to the reference medicine Methotrexate Pfizer. Therefore, the Medical Products Agency in Sweden decided that, as for Methotrexate Pfizer 2.5 mg, the benefits are greater than its risks and recommended that it can be approved for use.

Methotrexate Orion Pharma 10 mg is similar to a reference medicine containing the same active substance, but in another strength. The company has provided additional own data to demonstrate the safety and efficacy of Methotrexate Orion Pharma 10 mg 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 Methotrexate Orion Pharma'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 Methotrexate Orion Pharma?

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

The marketing authorisation for Methotrexate Orion Pharma was granted on 2017-01-20 in Sweden.

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

This summary was last updated in 2017-02.