

Summary Public Assessment Report

Fosfomycin Pharmexon (fosfomycin trometamol)

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(fosfomycin trometamol)
Granules for oral solution, 3 g

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

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

What is Fosfomycin Pharmexon and what is it used for?

Fosfomycin Pharmexon is a medicine with ‘well-established use’. This means that the medicinal use of the active substance of Fosfomycin Pharmexon is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

Fosfomycin Pharmexon is used in the prevention and treatment of uncomplicated infections of the bladder.

How does Fosfomycin Pharmexon work?

Fosfomycin Pharmexon contains the active substance fosfomycin trometamol. Fosfomycin trometamol is an antibiotic that works by killing bacteria which can cause infections. Fosfomycin Pharmexon is not suitable for the treatment of children below 12 years of age.

How is Fosfomycin Pharmexon used?

The pharmaceutical form of Fosfomycin Pharmexon is granules for oral solution.

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 Fosfomycin Pharmexon have been shown in studies?

As fosfomycin trometamol is a well-known substance, and its use in the prevention and treatment of acute uncomplicated bladder infections is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of fosfomycin trometamol in the prevention and treatment of uncomplicated bladder infections.

What are the possible side effects of Fosfomycin Pharmexon?

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

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

Why is Fosfomycin Pharmexon approved?

The use of Fosfomycin Pharmexon to treat and prevent uncomplicated bladder infections is well-established in medical practice and documented in the scientific literature. No new or unexpected safety concerns arose from these applications. Therefore, the Medical Products Agency in Sweden decided that Fosfomycin Pharmexon'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 Fosfomycin Pharmexon?

A risk management plan has been developed to ensure that Fosfomycin Pharmexon 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 Fosfomycin Pharmexon, 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 Fosfomycin Pharmexon

The marketing authorisation for Fosfomycin Pharmexon was granted on 2018-07-27 in Sweden.

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

This summary was last updated in 2018-08