

Package leaflet: Information for the user

Fosfomycin 3 g, granules for oral solution Fosfomycine Trometamol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4

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1. What Fosfomycin is and what it is used for

Fosfomycin granules for oral solution belongs to a group of medicines known as antibiotics. It works by killing bacteria, which can cause infections.

Fosfomycin is used to treat or prevent infections of the bladder.

Fosfomycin is not suitable for the treatment of children younger than 12 years of age.

2. What you need to know before you take Fosfomycin

Do not take Fosfomycin:

- if you are allergic to fosfomycin or any of the other ingredients of this medicine (listed in section 6);
- if you suffer from severe kidney problems;
- if you are undergoing haemodialysis (a procedure used to clean the blood by filtering out wastes and extra fluids, when the kidneys are not functioning);

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Fosfomycin, especially:

- if you have an intolerance to some sugars (see below);
- if you have previously experienced diarrhoea upon administration of any other antibiotics.

Children and adolescents

Do not give this medicine to children younger than 12 years of age, as its safety has not been established.

Other medicines and Fosfomycin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially a medicine called **metoclopramide** (a medicine to stop you from feeling sick) as this may have an affect on Fosfomycin.

Fosfomycin with food and drink

Fosfomycin should be taken on an empty stomach, preferably before bedtime, after emptying the bladder. The contents of a sachet should be dissolved in a glass of water and taken immediately.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

It is preferable to avoid the use of Fosfomycin during pregnancy. Your doctor will decide whether you should use Fosfomycin.

Small amounts of this medicine may pass into the breast milk and may affect the baby. Therefore, your doctor will decide whether you should use Fosfomycin while breast-feeding.

Driving and using machines

You may experience side effects such as dizziness or fatigue which may affect your ability to drive or use machines. Do not drive or use machines if you are affected.

Fosfomycin granules for oral solution contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Fosfomycin

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults including older people

The recommended dose is one sachet (3 g) of Fosfomycin as a single dose.

Use in children and adolescents

Fosfomycin should not be used in children younger than 12 years of age.

Route and methods of administration

Fosfomycin should be taken orally, on an empty stomach, preferably before bedtime, after emptying the bladder. The contents of the sachet should be dissolved in half a glass of water.

If you take more Fosfomycin than you should

If you accidentally take more than your prescribed dose, contact your doctor or nearest hospital.

If you forget to take Fosfomycin

If you forget to take a dose, take one as soon as you remember.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Fosfomycin

Do not stop taking Fosfomycin because you feel better. It is important to take this medicine for as long as the doctor has told you to, otherwise the infection might come back.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

While taking Fosfomycin if you develop any of the following symptoms **you should contact your doctor immediately**:

- anaphylactic shock: a life threatening type of allergic reaction (its frequency cannot be estimated from the available data). The signs may include a sudden onset of rash, itching or hives on the skin and or shortness of breath, wheezing or trouble breathing.
- serious allergic reaction which causes swelling of the face, lips, tongue or throat with breathing difficulties (angioedema) (its frequency cannot be estimated from the available data);
- faster heart beat (tachycardia) (its frequency is rare, may affect up to 1 in 1,000 people)
- mild to severe abdominal cramps, bloody stools and /or fever may mean that you have an infection of the large intestine (pseudomembranous colitis) (its frequency cannot be estimated from the available data).

These are very serious side effects. You may need immediate medical attention.

Other side effects

If any of the following side effects occur, contact your doctor as soon as possible:

Common (may affect up to 1 in 10 people):

- Headache;
- Dizziness;
- Indigestion;
- Infection of the female genital organs with symptoms like inflammation, irritation, itching (vulvovaginitis).

Uncommon (may affect up to 1 in 100 people):

- Tingling or numbness;
- Diarrhoea;
- Nausea;
- Vomiting;
- Stomachache;
- Rash;
- Tiredness.

Rare (may affect up to 1 in 1,000 people):

- Itching.

Not known (frequency cannot be estimated from the available data):

- Allergic reactions.
- Low blood pressure.
- Asthma, with symptoms such as wheezing, shortness of breath, coughing.

Reporting side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

5. How to store Fosfomycin

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after <EXP>. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

The content of one sachet should be poured into a glass and 50-75 ml of water or other aqueous drink should be added to obtain a uniform opalescent solution. If necessary, the solution may be stirred. The solution should be taken immediately after being prepared'

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Fosfomycin granules for oral solution contains:

- The active substance is fosfomycin trometamol. Each sachet contains 5.631 mg fosfomycin trometamol, equivalent to 3.000 g fosfomycin.
- The other ingredients are: orange flavour consisting of maltodextrin, dextrose monohydrate, acacia (E414), anhydrous citric acid (E330), butylhydroxyanisole (E 320); saccharin sodium, sucrose, calcium hydroxide.

What Fosfomycin granules for oral solution looks like and contents of the pack

White, off-white granules in a single-dose sachet.

Fosfomycin granules for oral solution are available in packs of:

Paper/LDPE/Alu/LDPE sachet

1 sachet of 8 g (3 g of fosfomycin)

2 sachets of 8 g (3 g of fosfomycin)

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Mercury Pharmaceuticals Limited

Capital House, 1st Floor,

85 King William Street,

London EC4N 7BL,

United Kingdom

Manufacturer

Special Product's Line S.p.A.

Via Fratta Rotonda Vado Largo, 1

03012 Anagni, Italy

This medicinal product is authorised in the Member States of the EEA under the following names:

United Kindom: Fosfomycin 3g granules for oral solution

This leaflet was last approved in November 2017.