



Fosfoseptic 3 g granules for oral solution

Fosfomycin 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What **Fosfoseptic** is and what it is used for
2. What you need to know before you use **Fosfoseptic**
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1. What Fosfoseptic is and what it is used for

Your medicine contains the active substance fosfomycin trometamol. **Fosfoseptic** is an antibiotic used for the treatment of acute, uncomplicated lower urinary tract infections (UTI) caused by pathogens sensitive to fosfomycin in women and girls over the age of 12 years.

Fosfomycin is used for prophylaxis of urinary tract infections in diagnostic and surgical procedures involving the lower urinary tract in adult men and women.

2. What you need to know before you take Fosfoseptic

Do not take Fosfoseptic:

- if you are allergic to fosfomycin trometamol or any of the other ingredients of this medicine (listed in section 6);
- If you have severe renal insufficiency (creatinine clearance < 10ml/min);
- If you are on hemodialysis.

Warnings and precautions

Talk to your doctor or pharmacist before taking **Fosfoseptic**.

In association with the use of almost all broad-spectrum antibacterial agents, including fosfomycin trometamol, there have been reports of antibiotic-associated diarrhea. It is important to consider this in patients developing severe diarrhea during or after fosfomycin trometamol use. In this situation an appropriate treatment should be immediately initiated. Drugs inhibiting peristalsis are contraindicated in these cases.

Children and adolescents

The safety and efficacy of Fosfoseptic 3 g in children below the age of 12 years has not been established.

Other medicines and Fosfoseptic

Tell your doctor or pharmacist if you are taking, have recently taken

or might take any other medicines.

It is important to know that concomitant administration of metoclopramide lowers serum and urinary concentrations of fosfomycin, therefore it should be avoided. It is especially important to inform your doctor if you are taking other medicines that increase gastrointestinal peristalsis and may cause similar effects.

Fosfoseptic with food and drink

Food may delay the absorption of the active substance causing mild reduction in the peak plasma and urinary levels. Therefore you should take this medicine on an empty stomach (2-3 hours after meals), preferably after bladder emptying.

Pregnancy, breast-feeding and fertility

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.

Your doctor will decide if you should be taking this medicine if you are pregnant or breast-feeding.

Observations in pregnant women (between 300 and 1000 pregnant women) show no harmful effects for the fetus or the newborn infant (or malformations or fetal/neonatal toxicity of fosfomycin trometamol).

It is not known if fosfomycin/fosfomycin metabolites are excreted in human breast milk. Fosfomycin is excreted at a low level after a single injection administration. A single oral dose of fosfomycin can be used during breast-feeding.

Driving and using machines

No data exist that the medicinal product influences attention or reaction time. There have been reports of dizziness which may affect some patients' ability to drive and use machines.

Fosfomycin contains sucrose. If you have fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase deficiency, talk to your doctor before taking this medicine.

3. How to take Fosfoseptic

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

Your doctor will determine your dose during the treatment.

Adults

The recommended dose for the treatment of uncomplicated lower urinary tract infections in women and girls above 12 years is a single dose **Fosfoseptic** 3 g sachet.

The recommended dose for prophylaxis of urinary tract infections in diagnostic and surgical procedures involving the lower urinary tract in adult men and women is two doses of Fosfoseptic 3 g sachet; the first dose of Fosfoseptic 3 g sachet should be taken 3 hours before the surgical procedure, and one dose Fosfoseptic 3 g sachet should be taken 24 hours after surgery

Method of administration

Fosfoseptic is for oral administration and should be taken on an empty stomach, preferably before bedtime, after emptying the bladder. The contents of one sachet should be dissolved in a glass of water and taken immediately after that.

If you take more Fosfoseptic than you should

When Fosfoseptic is in a single sachet pack, the risk of overdosing is practically non-existent.

The following overdosage reactions with Fosfoseptic have been observed: vestibular loss, impaired hearing, metallic taste and general decline in taste perceptions.

If you have taken more Fosfoseptic than you should, it would be sufficient to stimulate the drug elimination in the urine by drinking adequate amount of liquids.

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

4. Possible side effects

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

The most common adverse drug reactions after administration of single dose fosfomycin trometamol affect the gastrointestinal tract, mainly as diarrhea. These reactions are usually short-term and resolve spontaneously.

The following adverse reactions may occur during treatment with this medicine:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

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

Very rare: may affect up to 1 in 10,000 people

Not known: frequency cannot be estimated from the available data

Infections and infestations:

Common: vulvovaginitis (inflammation of female genitalia)

Immune system disorders:

Not known: anaphylactic reactions including anaphylactic shock (severe allergic reaction causing difficulties breathing or dizziness), hypersensitivity.

Nervous system disorders:

Common: headache, dizziness

Uncommon: paresthesia (tingling, numbness and other sensations in the skin)

Cardiac disorders:

Rare: tachycardia (fast heart rate)

Respiratory, thoracic and mediastinal disorders:

Not known: asthma

Gastrointestinal disorders:

Common: diarrhea, nausea, dyspepsia (indigestion)

Uncommon: vomiting, abdominal pain

Not known: antibiotic-associated colitis (inflammation of the colon causing abdominal pain and diarrhea/constipation)

Skin and subcutaneous tissue disorders:

Uncommon: rash, urticaria, pruritus

Not known: angioedema (severe allergic reaction causing swelling of the face or throat)

General disorders and administration site conditions:

Uncommon: fatigue

Vascular disorders:

Not known: hypotension (low blood pressure)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fosfoseptic

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

Do not store above 25 °C.

Keep this medicine in its original packaging.

Do not use this medicine after the expiry date which is stated on the sachet after Exp. The expiry date refers to the last day of that month.

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 Fosfoseptic contains

- The active substance is Fosfomycin trometamol 5,631 g (equivalent to 3 g fosfomycin)
- The other ingredients are: sucrose, saccharin sodium, orange flavouring, mandarine flavouring (maltodextrin, arabic gum (E 414), citric acid (E 330), sodium citrate (E 331), Butylated hydroxyanisole (E 320)

What Fosfoseptic looks like and contents of the pack

Almost white granules with citrus flavour
Granules for oral solution 8,0 g in paper/aluminium/polyethylene sachet.

Each pack contains 1 or 2 sachets.

Marketing Authorisation Holder and Manufacturer

Adipharm EAD
130 Simeonovsko shosse Blvd.
1700 Sofia
Bulgaria

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