

Package leaflet: Information for the patient

UROSEPTIC 3 g granules for oral solution in sachets

Fosfomicin

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 Uroseptic is and what it is used for
2. What you need to know before you take Uroseptic
3. How to take Uroseptic
4. Possible side effects
5. How to store Uroseptic
6. Contents of the pack and other additional information

1. What Uroseptic is and what it is used for

Uroseptic contains the active substance fosfomicin (as fosfomicin trometamol). It is an antibiotic that works by killing bacteria which can cause infections.

Antibiotics are used to treat bacterial infections and not to treat viral infections such as flu or a cold.

It is important to follow your doctor's directions regarding prescribed dose, dosing interval and treatment length.

Do not store or reuse this medicine. If, once the treatment is over, there is any sachet surplus, please return it to the pharmacy for its proper disposal. Do not throw away any medicines via wastewater or household waste.

Uroseptic is used to treat uncomplicated infection of the bladder in women and female adolescents.

2. What you need to know before you take Uroseptic

Do not take Uroseptic

- if you are allergic to fosfomicin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Uroseptic if you suffer from one of the following disorders:

- persistent infections,
- previously had diarrhoea after taking any other antibiotics.

Conditions you need to look out for

Uroseptic can cause serious side effects. These include allergic reactions and an inflammation of the large intestine. You must look out for certain symptoms while you are taking this medicine, to reduce the risk of any problems. See "Serious side effects" in section 4.

Children and adolescents

Do not give this medicine to children less than 12 years of age, as its safety and efficacy have not been established in this age group.

Other medicines and Uroseptic

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This is especially important if you are taking:

- **metoclopramide** or other medicinal products that increase the movement of food through the stomach and intestines, because they may reduce the uptake of fosfomicin by your body,
- **anticoagulants**, as their ability to prevent your blood from clotting might be altered by fosfomicin and other antibiotics.

Uroseptic with food

Food may delay the absorption of fosfomicin. Therefore, this medicinal product should be taken on an empty stomach (2-3 hours before or 2-3 hours after a meal).

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.

If you are pregnant your doctor will only give you this medicine when it is clearly needed.

Breast-feeding mothers can take a single oral dose of this medicine.

Driving and using machines

You may experience side effects, such as dizziness, which may affect your ability to drive or use machines.

Uroseptic contains glucose and sulphites

This medicine contains glucose. If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicine.

This medicine contains sulphites. May rarely cause severe hypersensitivity reactions and bronchospasm (sudden feeling of choking). This medicine contains less than 1 mmol sodium (23 mg) per sachet, that is to say essentially "sodium-free".

3. How to take Uroseptic

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

In case of treatment of uncomplicated infection of the bladder, in women and female adolescents the recommended dose is 1 sachet of Uroseptic (3 g fosfomicin).

Use in patients with renal impairment

This medicine should not be used in patients with severe renal impairment (creatinine clearance < 10 ml/min).

Use in children and adolescents

This medicine should not be used in children less than 12 years of age.

Method of administration

For oral use.

Take this medicine orally, on an empty stomach (2-3 hours before or 2-3 hours after a meal), preferably before going to bed after emptying the bladder. Dissolve the content of one sachet in a glass of water and drink immediately.

If you take more Uroseptic than you should

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

In case of overdose or accidental intake, immediately consult your doctor or pharmacist indicating the drug and the amount ingested.

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.

Serious side effects

While taking Uroseptic, if you develop any of the following symptoms you should stop taking the medicine and contact your doctor immediately:

- anaphylactic shock, a life threatening type of allergic reaction (the frequency is unknown). Symptoms include a sudden onset of rash, itching or hives on the skin and or shortness of breath, wheezing or difficulty in breathing,
- swelling of the face, lips, tongue or throat with breathing difficulties (angioedema) (the frequency is unknown),
- moderate to severe diarrhoea, abdominal cramps, bloody stools and/or fever may mean that you have an infection of the large intestine (antibiotic-associated colitis) (the frequency is unknown). Do not take medicines against diarrhoea that inhibit the bowel movements (antiperistaltic).

Other side effects

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

- headache
- dizziness
- diarrhoea
- nausea
- indigestion
- abdominal pain
- infection of the female genital organs with symptoms like inflammation, irritation, itching (vulvovaginitis).

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

- vomiting
- rash
- urticaria
- itching

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

- allergic reactions.

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.

5. How to store Uroseptic

Store below 30 °C.

Uroseptic should be taken immediately after its dissolution.

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.

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 Uroseptic contains

- The active substance is fosfomicin. Each sachet contains 5,631 g of fosfomicin trometamol, equivalent to 3 g of fosfomicin.
- The other ingredients are glycine, sucralose, aerosil, povidone and lemon flavour [contains glucose (in maltodextrine from corn) and sulphites)].

What Uroseptic looks like and contents of the pack

White to off-white granules, with a characteristic smell of lemon, for being dissolved in water.

Each carton contains 1 or 2 sachets of granules.

Marketing Authorisation Holder and Manufacturer

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