

URODAY 3G GRANULES FOR ORAL SOLUTION

Fosfomycin Trometamol 5.631g (equivalent to 3g Fosfomycin)

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What Uroday is used for

Uroday is used to treat uncomplicated infection of the bladder or urinary tract infections in females of 18 years of age and older.

How Uroday works

Uroday contains the active substance Fosfomycin (as Fosfomycin trometamol). It works by killing bacteria which can cause infections or preventing their growth.

Before you use Uroday

When you must not use it

- If you are hypersensitive to fosfomycin trometamol or any of the other ingredients of Uroday.
- The use of Uroday is not recommended if you have severe kidney problems (creatinine clearance below 10ml/min).
- Do not use Uroday in children under 12 years of age.
- Uroday contains sugar: it is not recommended if you have rare hereditary problems of fructose intolerance, with glucose-galactose malabsorption or sucrose-isomaltase insufficiency.
- Uroday should only be used during pregnancy if clearly necessary.
- Do not take Uroday if you are breast-feeding unless strictly necessary.

Before you start use it

- Always ask your doctor or pharmacist before using this product if you have any doubts.

Taking other medicines

Some medicines and Uroday may interfere with each other. These include:

- metoclopramide or other drugs that increase the movement of food through the stomach and intestines, because they may reduce the uptake of Fosfomycin by your body and reduce the effect of Uroday.

- anticoagulants, as their ability to prevent your blood from clotting might be altered by Fosfomycin and other antibiotics.

It is recommended that Uroday should be taken 2 -3 hours after other medicines.

How to use Uroday

How much to use

The recommended dose is one sachet of Uroday (3g Fosfomycin).

After taking Uroday, improvement should be expected within 2 or 3 days. If your symptoms do not improve, you should contact your doctor.

When to use it

Uroday must only be administered orally on an empty stomach preferably at bedtime, after emptying the bladder.

How long to use it

Take this medicine exactly as your doctor has told you.

If you forget to use it

Do not take a double dose to make up for the missed dose.

If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Rehydration is recommended in order to support the elimination of Fosfomycin via urine.

While you are using it

Things you must do

The dose must be dissolved in a glass of water (50 - 75ml) and administered soon after dissolving.

Things you must not do

- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not give this medicine to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

- Since Uroday can trigger dizziness, this could affect the ability to drive or operate machinery.
- Hypersensitive reactions may occur during treatment with Fosfomycin and maybe life threatening.
- Do not take Uroday if these reactions occurred. Please seek the medical treatment from your doctor.
- If severe and persistent diarrhoea occur during or after antibiotic treatment, please tell your doctor so that appropriate therapy can be initiated immediately. Do not take medicines against diarrhoea that inhibit the bowel movements (antiperistaltics).

Side effects

The most common side effects are those which affect the gastrointestinal tract, primarily diarrhoea.

Other side effects:

Common (may affect up to 1 in 10 people)

- Infection of the female genital organs with symptoms such as inflammation, irritation, itching (vulvovaginitis)
- headache
- dizziness
- diarrhoea
- nausea
- indigestion
- stomach pain

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Uncommon (may affect up to 1 in 100 people)

- vomit
- rash
- hives
- itching

Not known (frequency cannot be estimated from available data)

- life threatening type of allergic reaction: sudden onset of rash, itching or hives on the skin, shortness of breath, wheezing or trouble breathing (anaphylactic shock);
- swelling of the face, lips, tongue, or throat with breathing difficulties (angioedema);
- mild to severe abdominal cramps, bloody stools and /or fever (antibiotic-associated colitis)

If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Uroday

Storage

Keep out of the reach and sight of children.

Store below 30°C. Use immediately after opening/ dilute with water. For single use. Discard any unused portion.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

Appearance: White powder in sachet.

Odor: Orange, tangerine scented.

Appearance of solution: It should be homogeneous and opaque with an orange, tangerine.

Each sachet contains 5.631 g fosfomycin trometamol equivalent to 3 g fosfomycin as active substance.

URODAY is available in pack size of 1 sachet/box.

Ingredients

- Active ingredient(s)
Fosfomycin Trometamol
- Inactive ingredients
Sugar, sodium saccharin, aerosil 200, orange flavor and mandarin flavor.

MAL number(s):

MAL*****

Manufacturer

Neutec İlaç San. Tic. A.Ş.

1. Organize Sanayi Bölgesi

1. Yol No: 3 ve 2 Yol No:2

Arifiye/Sakarya/Turkey

Product Registration Holder

Averroes Pharmaceuticals Sdn. Bhd.

03-08-01 & 03-09-01, Block 3, Presint

Alami, Worldwide Business Centre II,

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Malaysia

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