

PATIENT INFORMATION LEAFLET

UROCARE Sachet

For oral administration

Active ingredient:

5.631 grams of fosfomycin trometamol is equivalent to 3 grams fosfomycin for each 8 grams of sachet.

Excipients:

Orange flavour, mandarin flavour, saccharin, sucrose

Read this PATIENT INFORMATION LEAFLET carefully before you start using this medicine since 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. Do not pass it on to others.*
- *When you go to a doctor or hospital during the use of this medicine, tell your doctor that you are using this medicine.*
- *Please follow these written instructions exactly. Do not use **higher or lower dose** than the dose recommended to you about the drug.*

In this leaflet:

- 1. What UROCARE is and what it is used for?***
- 2. Things should be considered before you take UROCARE***
- 3. How to take UROCARE?***
- 4. What are the possible side effects?***
- 5. Storage of UROCARE***

Topics are included.

1. What UROCARE is and what it is used for?

- UROCARE contains 3 grams of fosfomycin equivalent to 5,631 grams of fosfomycin trometamol as the active ingredient.
- UROCARE is included in the group of systemically administered antibiotics.
- UROCARE is located in a carton box containing 1 sachet in an 8 g three-layer pet-aluminum-polyethylene package.

- UROCARE is used in the treatment of urinary tract infections (inflammatory microbial diseases) caused by fosfomycin sensitive bacteria. It is also used with the purpose of preventing urinary tract infections caused by diagnostic or surgical procedures related to the urinary tract.

2. Things should be considered before you take UROCARE

Do not take UROCARE in the following situations.

if you;

- are hypersensitive (allergic) to the active substance fosfomycin or any of excipients of UROCARE,
- have severe kidney failure, if you are a hemodialysis patient,
- have been told by your doctor that you have tolerance to some sugars, contact your doctor before taking this medicinal product.

Take UROCARE carefully in the following situations.

If you;

- Have diabetes or if you are on a diet, please note that each UROCARE contains 2.107 g sugar.
- Have upper urinary tract infection such as inflammation of the kidneys (nephritis, pyelonephritis, etc.) it is suggested not to use.
- Have moderate to mild renal insufficiency
- In use of almost all antibacterial medicines, antibiotic-induced diarrhea (diarrhea) of varying severity can be seen. If you experience serious, sustained or bloody diarrhea (diarrhea) during or after the use of your medicine; in which case bacterial diarrhea (Clostridium difficile-induced diarrhea) may be the case.

If any of these cautions apply to you even at any time in the past, please consult your doctor.

Taking UROCARE with food and drink

Taking with food may delay the absorption of the active substance, causing a slight drop in blood and urine levels.. So,it is preferred to take this drug on an empty stomach or after 2-3 hours of meals.

Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine.

The use of UROCARE during pregnancy can be considered in case of necessity.

During treatment, consult your doctor or pharmacist if you notice that you are pregnant.

Breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

After a single oral dose, fosfomycin can be used during lactation.

Driving and using machines

No specific studies have been conducted, but patients should be informed that dizziness reports have been received. This may affect the ability of some patients to drive and use the machine.

Important information about some of the excipients of UROCARE

UROCARE contains sugar as excipients. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product

Taking with other medicines

Do not use the following drugs while you are using UROCARE:

- As serum and urine concentrations may decrease an anti-nausea drug, metoclopramide
- Drugs that increase gastrointestinal motility as it may increase diarrhea
- Vitamin K antagonists because they increase activity when used with antibiotics

If you are currently using prescription or non-prescription medications or have recently used, please inform your doctor or pharmacist about these.

3. How to take UROCARE?

Instructions for appropriate use and dose/frequency of application:

UROCARE should be used when recommended by you doctor as prescribed.

UROCARE is used as a single dose in urinary tract infections.

Recommended application is, dissolving the content of product in a glass of water and to drink after dissolved.

UROCARE is the recommended form of urinary tract infections, including lower urinary tract infections in adult males and females, prior to diagnosis and surgical intervention; the first dose should be taken 3 hours before surgery and the second dose should be taken 24 hours after surgery.

Route of administration and method:

The UROCARE content is dissolved by stirring in a glass of water at room temperature, they are all drunk immediately after they are prepared.

UROCARE should be taken on an empty stomach (2-3 hours after meals). It is recommended to use the oral route before bedtime before bedtime and after the bladder has been emptied.

Various age groups:

Use in children:

Since the experience is limited for its use in children under 12 years and in babies, usage is not recommended.

Use in elderly:

There is not a special warning about the usage in elderly.

Special use cases:**Renal insufficiency:**

It should not be used in severe renal insufficiency.

Liver failure:

There is no special use.

Please ask your doctor or pharmacist if you think that the effect of UROCARE is too strong or too weak.

If you take more UROCARE than you should

It is important to take the recommended amount of the drug by your doctor.

If you take more UROCARE than you should, please talk with a doctor or pharmacist.

If you forget to take UROCARE

UROCARE is used as a single dose, so if you forget to take a dose, take the missed dose as soon as you remember.

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

Effects that may occur when treatment with UROCARE is terminated

If you are considering stopping UROCARE treatment, consult your doctor first.

If you have any other questions about the use of this product, do not worry about your doctor.

4. What are the possible side effects?

Like all medicines, UROCARE can cause side effects in people who are sensitive to its ingredients.

The frequency ratings of side effects are as follows.

Very common: more than 1 in 10 people

Common: less than 1 in 10 people, more than 1 in 100 people

Uncommon: less than 1 in 100 people, more than 1 in 1,000 people

Sparse: less than 1 in 1,000 people, more than 1 in 10,000 people

Very rare: less than 1 in 10,000 people

Unknown: The degree of frequency can not be predicted from the current data

Common:

- Vaginitis (vaginitis)
- Headache
- dizziness

- Diarrhea
- Nausea
- Indigestion

Uncommon:

- Feeling tingling and stinging
- Vomiting
- Abdominal pain
- Skin rash
- Small red stains on skin
- Dermation itching
- General fatigue state

Rare:

- The number of heart beats per minute is higher than normal.

Unknown:

- Responses to hypersensitivity as far as shoga (rash, itching, sweating, dizziness, swelling in the tongue, lip and parenchyma, blockage of the airway)
- Hearing or short breathing, or feeling of tightness in the chest (asthma)
- Antibiotic-induced diarrhea
- Swelling of the skin and mucosa (angioedema)
- Reduction of blood pressure

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE UROCARE

Keep UROCARE in places where children can not see, can not reach and in its package.

Store at room temperature below 25 ° C.

Keep it in its original package.

Use in accordance with the expiration date.

Please do not use UROCARE after the expiration date on package.

Do not use UROCARE if you notice any product and/or packaging defects.

Marketing Authorisation Holder:

Drogsan İlaçları San. ve Tic. A.Ş.
Oğuzlar Mah. 1370. sok. 7/3
Balgat-ANKARA

Manufacturer:

Drogsan İlaçları San. ve Tic. A.Ş.
Çubuk-ANKARA

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