

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS
(PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only

Monurol[®]

Powder for Oral Solution

Active ingredient:

Each sachet contains: 3 g fosfomycin (as trometamol).

For the list of the additional ingredients, see section 6. See also 'Important information about some of the medicine's ingredients' in section 2.

Read the entire leaflet carefully before using the medicine.

This leaflet contains concise information about the medicine. If you have any further questions, please refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is the medicine intended for?

Monurol is intended for:

- Treatment of acute uncomplicated infection of the urinary bladder (cystitis) in women and female adolescents.
- Preventive antibiotic treatment before taking a prostate tissue sample through the rectum (transrectal biopsy) in an adult man.

Therapeutic group: antibiotic.

Monurol is an antibiotic that contains the active substance fosfomycin (as fosfomycin trometamol), which kills the bacteria that can cause infections.

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients the medicine contains (for the list of the additional ingredients, see section 6).

Special warnings regarding the use of the medicine:

Before treatment with Monurol tell the doctor if:

- You suffer from persistent and recurrent infections of the bladder.
- You previously suffered from diarrhea after taking any other antibiotics.
- You suffer or have suffered in the past from impaired kidney function or are undergoing hemodialysis treatment.

Additional warnings

Conditions requiring paying attention to:

The medicine can cause serious side effects: These effects include allergic reactions and inflammation of the large intestine. Pay attention to certain symptoms while you are taking the medicine, to reduce the risk of any problems. See 'Serious side effects' in section 4.

Children and adolescents:

This medicine is not intended for children under the age of 12, since the safety and efficacy of the medicine in this age group has not been determined.

Drug interactions:

If you are taking or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Especially if you are taking:

- **Metoclopramide** (for treatment of nausea and vomiting) or other medicines that increase the movement of food through the digestive system, as they may reduce the absorption of the medicine in your body.
- **Anticoagulants**, as their ability to prevent blood clotting may be altered by taking Monurol or other antibiotics.

Use of the medicine and food:

Food may delay the absorption of the medicine, therefore the medicine should be taken on an empty stomach (2-3 hours before a meal or 2-3 hours after a meal).

Pregnancy and breastfeeding:

- If you are pregnant, think you are pregnant, are planning a pregnancy or are breastfeeding, consult the doctor before using the medicine.
- If you are pregnant, the doctor will tell you to take the medicine only if it is clearly needed.
- Breastfeeding women can receive a single dose of the medicine, on the doctor's instruction. The medicine passes into the breastmilk in small quantities.

Driving and use of machinery:

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

Do not drive or operate machinery if you feel dizzy or experience other side effects that might affect your ability to drive and/or operate machinery.

Important information about some of the medicine's ingredients:

- *Sodium*: the medicine contains less than 23 mg of sodium per sachet, therefore is considered as "sodium-free".
- *Sucrose*: each sachet contains approximately 2.213 g sucrose. If you have intolerance to some sugars, contact the doctor before taking the medicine.
- *Sulfites*: in rare cases, they may cause severe hypersensitivity reactions and bronchospasm.
- *Saccharin*: each sachet contains approximately 16 mg saccharin.

3. How to use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine. The dosage and manner of treatment will be determined by the doctor only.

This medicine is not intended for children under the age of 12.

The standard dosage is usually:

For treatment of acute uncomplicated infection of the urinary bladder in women and female adolescents - this medicine is administered as a single dose (one sachet of Monurol).

For preventive antibiotic treatment in transrectal prostate biopsy - one sachet 3 hours before the procedure and one sachet 24 hours after the procedure.

Impaired kidney function

Patients with severe impairment of kidney function or patients undergoing hemodialysis - the medicine should not be used, except after patient benefit-risk assessment by the doctor.

Children and adolescents

This medicine is not intended for children under the age of 12.

Do not exceed the recommended dose.

How to take the medicine:

The medicine is intended to be administered orally.

Take the medicine on an empty stomach (about two or three hours before or after a meal), preferably before going to bed, after emptying the bladder.

Pour the entire contents of the sachet into a full glass of water and mix well until the powder is dissolved. Drink the entire contents of the glass immediately.

After you take Monurol, improvement is to be expected within 2-3 days.

If you accidentally took a higher dosage: if you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room, and bring the medicine package with you.

Complete the treatment as instructed by the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions concerning the use of the medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, the use of Monurol may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

Serious side effects

Stop the treatment with the medicine and refer to a doctor immediately if one or more of the following symptoms occur during the treatment:

- Anaphylactic shock, a type of life-threatening allergic reaction (*unknown frequency*). The symptoms include a sudden onset of rash, itching or hives on the skin and/or shortness of breath, wheezing or breathing difficulties.
- Swelling of the face, lips, tongue or throat with breathing difficulties (angioedema) (*unknown frequency*).
- Moderate to severe diarrhea, abdominal cramps, bloody stools and/or fever, may indicate that you have an infection of the large intestine (antibiotic-associated colitis) (*the frequency is unknown*). Do not take medicines against diarrhea that inhibit the bowel movements.

Additional side effects

Common side effects (appear in 1-10 users out of 100):

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

Uncommon side effects (appear in 1-10 users out of 1,000):

Vomiting, rash, hives (urticaria), itching.

Side effects of unknown frequency (effects whose frequency has not yet been determined):

Allergic reactions.

If a side effect appears, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads to an online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a closed place out of the reach and sight of children and/or babies, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.

Storage conditions:

Store below 25°C.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Sucrose, mandarin flavour, orange flavour, saccharin.

What does the medicine look like and what does the package contain?

White powder for preparation of an oral solution, in a single dose laminate sachet.

The sachet is a four-layer laminate of: paper/polyethylene/aluminum/polyethylene.

The medicine is marketed in a cardboard packaging containing one sachet.

Manufacturer: Zambon Switzerland Ltd., Via Industria 13, CH- 6814 Cadempino, Switzerland

Registration Holder: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301, Israel.

Medicine registration number in the National Medicines Registry of the Ministry of

Health: 107-93-28982

Revised in May 2024.