

**Patient Leaflet in Accordance with the Pharmacists' Regulations (Preparations) – 1986**

This medicine is sold with a doctor's prescription only

**Monurol  
Powder for Oral Solution  
Sachet**

**Active ingredient:**

Each sachet contains: Fosfomycin (as trometamol) 3 g

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 this entire leaflet carefully before using the medicine.**

This leaflet contains concise information about the medicine. If you have further questions, 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?**

- For single-dose treatment of acute uncomplicated urinary tract infection .
- For preventive treatment of infections subsequent to surgical or diagnostic procedures of the lower urinary tract.

**Therapeutic group:** antibiotic medicine.

**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).
- You suffer from severe kidney failure (creatinine clearance of less than 10 ml/min).
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- You are a dialysis patient.

**Special warnings regarding the use of this medicine:**

**Before treatment with Monurol tell the doctor if:**

- You suffer from persistent bladder infections.
- You previously suffered from diarrhea after taking any antibiotic medicine.
- You suffer or have suffered in the past from impaired kidney function.

**Additional warnings:**

**Conditions you need to pay attention to:**

The medicine may cause serious side effects. These effects include allergic reactions and inflammation of the large intestine. You must pay attention to 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 established.

**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:

- Medicines that increase motility in the digestive system, such as metoclopramide (anti-nausea). These medicines may reduce the absorption of the medicine in your body.
- Anticoagulants: their anticoagulant activity 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, planning a pregnancy or are breastfeeding, consult the doctor before using the medicine.

- If you are pregnant, the doctor will instruct 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 breast milk in small quantities.

**Driving and use of machinery:** the use of this medicine may cause side effects such as dizziness. Do not drive or operate machinery if you feel dizziness or other side effects that might impair your ability to drive and/or operate machinery.

**Important information about some of the medicine's ingredients:**

The medicine contains the following ingredients:

- **Sodium:** the medicine contains less than 23 mg sodium in each sachet and is therefore considered "sodium-free".
- **Sucrose:** each sachet contains approximately 2.2 g sucrose (sugar). If you have intolerance to certain sugars, inform the doctor before taking the medicine.
- **Sulphites:** may rarely 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 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 and/or for patients weighing less than 50 kg.

**The standard dosage is usually:**

For treatment of a urinary tract infection - this medicine is given as a single dose.

For preventive treatment of infections subsequent to surgical or diagnostic procedures - one sachet 3 hours before the surgical or diagnostic procedure and one sachet 24 hours after the surgical or diagnostic procedure.

**Do not exceed the recommended dose.**

**Manner of use:**

The medicine is intended for oral use.

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

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

After taking 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, proceed immediately to a doctor and bring the package of the medicine with you.

Complete the treatment course 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:**

**Proceed immediately to a doctor if you develop the following side effects and symptoms:**

- Anaphylactic shock: a type of life-threatening allergic reaction (the frequency of the side effect is unknown). The symptoms include a sudden onset of rash, itching or urticaria on the skin and/or shortness of breath, wheezing or breathing difficulties.
- Swelling of the face, lips, tongue or throat with breathing difficulties – angioedema (the frequency of the side effect is unknown).
- Moderate to severe diarrhea, abdominal cramps, bloody stools and/or fever: these symptoms may indicate that you might have an infection of the large intestine (antibiotic-associated colitis). The frequency of this side effect 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, digestion difficulties, abdominal pain, infection of the female genital organs (such as the vagina) with symptoms like inflammation, irritation, itching.

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

Vomiting, rash, urticaria/hives, 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 the doctor.**

##### **Reporting side effects:**

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](http://www.health.gov.il)) that 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 infants, 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 in an aluminum sachet. Each box contains one sachet.

**Registration holder:** Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301

**Manufacturer:** Zambon Switzerland Ltd., Switzerland.

**Medicine registration number in the National Medicines Registry of the Ministry of Health: 1079328982**

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