

Patient Leaflet according to the Pharmacists' Regulations  
(Preparations) - 1986

This medicine requires a doctor's prescription  
Please read the entire leaflet carefully before using this  
medicine

# MONUROL

## Powder for oral solution Sachet

### Composition:

#### Active ingredient

Each sachet contains: Fosfomycin (as trometamol) 3 g

#### Inactive ingredients

Sucrose, mandarin flavour, orange flavour, saccharin.

Each sachet contains approximately 2.2 grams of sucrose  
and 16 mg of saccharin.

### Therapeutic group: Antibiotic

### Therapeutic Activity:

The medicine is intended as a single dose treatment  
for urinary tract infection, as well as for the prevention of  
infections subsequent to surgical or diagnostic procedures  
of the lower urinary tract.

### When should this medicine not be used?

Do not use this medicine if you are hypersensitive to any  
of its ingredients.

Do not use this medicine if you suffer from kidney failure  
or if you are undergoing dialysis.

### Do not take this medicine without consulting a doctor before starting treatment, in the following cases:

If you are pregnant or breastfeeding.

If you suffer or have suffered in the past from impaired  
function of the kidneys/urinary system, or if you suffer from  
diabetes.

### How might this medicine affect your daily life?

The use of this medicine may cause dizziness. If you feel  
dizzy, caution should be exercised when driving a vehicle,  
operating dangerous machinery or performing any other  
activity that requires special vigilance.

### Warnings:

If you are sensitive to any type of food or medicine, inform  
your doctor before starting treatment with this medication.  
Monurol contains sugar (sucrose).

### Drug interactions:

If you are taking any other medications including non-  
prescription drugs and nutrition supplements, or if you have  
recently finished treatment with another drug, please notify  
your doctor in order to prevent any potential risks or a potential  
reduction in efficacy that may result from drug interactions.  
In particular, medicines of the following therapeutic groups  
may interact with your medicine: Antacids, calcium salts,  
medicines which increase gastrointestinal motility such as,  
metoclopramide (antiemetic).

### Side effects:

In addition to the desired effect of the medicine, side effects  
may also appear during the course of taking this medicine.  
These may include: diarrhea, headaches, stomach aches,  
nausea, vomiting, digestive disturbances, dizziness, rash,  
itching, urticaria/hives tingling, tiredness.

Most of these side effects usually pass within a short time.  
If these side effects persist and/or are bothersome, please  
consult your doctor.

### The following side effects require special attention:

Allergic reaction (severe rash and itching, edema, breathing  
difficulties), acute diarrhea during or after taking the  
medicine, vaginitis, increase in heart rate, decrease in  
blood pressure, shortness of breath – refer to your doctor  
immediately!

If at any time you experience side effects that are not  
mentioned in this leaflet or if you feel an adverse change in  
your general health, consult your doctor immediately!

### Dosage:

This medicine is usually not intended for infants and children  
under the age of 12 years nor for patients weighing less than  
50 kg.

Administer according to the doctor's instructions only. Do not  
exceed the recommended dose.

The usual recommended dosage is:

**For the treatment of urinary tract infection: This medicine  
should be administered as a single dose.**

**As preventive treatment:** One sachet 3 hours before surgical  
or diagnostic procedure and one sachet 24 hours afterwards.

### Directions for use:

Empty the entire contents of the sachet into a full cup of  
water or any other non-alcoholic beverage, and stir well until  
the powder is dissolved. Drink the entire contents of the cup  
immediately.

**This medicine should be taken on an empty stomach,  
about 2 to 3 hours before or after a meal, preferably  
before bedtime after emptying the urinary bladder.**

**After taking Monurol improvement should be expected  
within 2 to 3 days.**

### How can you contribute to the success of the treatment?

Complete the entire course of treatment as instructed by  
your doctor.

### Avoid poisoning!

This medicine, and all other medicines, must be stored in  
a safe place out of the reach of children and/or infants, to  
avoid poisoning.

If you have taken an overdose, or if a child has accidentally  
swallowed the medicine, proceed immediately to a hospital  
emergency room and bring the package of the medicine with  
you.

**Do not induce vomiting** unless explicitly instructed to do so  
by a doctor!

This medicine was prescribed for the treatment of your  
ailment; in another patient it may cause harm. **Do not give  
this medicine to your relatives, neighbours or acquaintances.  
Do not take medicines in the dark!** Carefully check the label  
and dose **each time** you take the medicine.

Wear your glasses if you need them.

### Storage:

This medicine should be stored below 25°C.

Even if stored properly according to the manufacturer's  
recommendations, all medicines have a limited shelf life.  
Please pay attention to the expiry date of your medicine! If you  
have any doubts, please consult the dispensing pharmacist.  
Do not store different medicines in the same container.

**Drug Registration Number:** 1079328982

### Manufacturer:

Zambon Switzerland Ltd., Switzerland

### Registration holder:

Rafa Laboratories Ltd., P.O.Box 405, Jerusalem 9100301

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