

# MONUROL 3G GRANULES

Fosfomycin trometamol 5.631g (equivalent to 3g Fosfomycin)

---

## What is in this leaflet

1. What MONUROL is used for
2. How MONUROL works
3. Before you use MONUROL
4. How to use MONUROL
5. While you are using it
6. Side effects
7. Storage and Disposal of MONUROL
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial number

## What MONUROL is used for

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

MONUROL is used as antibiotic prophylaxis for transrectal prostate biopsy in adult man.

## How MONUROL works

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

## Before you use MONUROL

### When you must not use it

- If you are hypersensitive to fosfomycin trometamol or any of the other ingredients of MONUROL.
- The use of MONUROL is not recommended if you have severe kidney problems (creatinine clearance below 10 ml/min).
- Do not use MONUROL in children under 12 years of age.
- MONUROL contains sucrose: it is not recommended if you have rare hereditary problems of fructose intolerance, with glucose-galactose malabsorption or sucrose-isomaltase insufficiency.

- MONUROL should only be used during pregnancy if clearly necessary
- Do not take MONUROL if you are breast-feeding unless strictly necessary.

### Before you start to use it

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

### Taking other medicines

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

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

## How to use MONUROL

### How much to use

For treatment of uncomplicated infection of the bladder or urinary tract infections in females of 18 years of age and older, the recommended dose is one sachet of MONUROL (3g Fosfomycin).

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

When used as antibiotic prophylaxis for transrectal prostate biopsy, the recommended dose is 1 sachet of MONUROL (3g fosfomycin) 3 hours prior to the procedure and 1 sachet of

MONUROL (3g fosfomycin) 24 hours after the procedure.

### When to use it

For treatment of uncomplicated infection of the bladder or urinary tract infections in females of 18 years of age and older, MONUROL 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 the urine.

## While you are using it

### Things you must do

The dose must be dissolved in a glass of water (50 – 75mL) or in another favourite non-alcoholic drink 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 MONUROL can trigger dizziness, this could affect the

# MONUROL 3G GRANULES

Fosfomycin trometamol 5.631g (equivalent to 3g Fosfomycin)

---

ability to drive or operate machinery.

- Hypersensitive reactions may occur during treatment with Fosfomycin and maybe life threatening.

Do not take MONUROL 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

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](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

## Storage and Disposal of MONUROL

### Storage

Store at room temperature not exceeding 30°C.

Keep out of the reach of children.

Do not exceed the expiry date plainly indicated on the packaging.

### Disposal

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

## Product Description

### What it looks like

Monurol is white granular with a characteristic odour of mandarin flavor.

### Ingredients

- Active ingredient: Fosfomycin trometamol
- Inactive ingredients: Saccharin, orange flavour, sucrose, mandarin flavour.

### MAL number

MAL20033481AZ

### **Manufacturer**

Zambon Switzerland Ltd.  
Via Industria 13 - 6814 Cadempino  
SWITZERLAND

### **Product Registration Holder**

EP PLUS GROUP SDN. BHD.  
Block C-3-1, Plaza Mont Kiara  
No 2, Jalan Kiara, Mont Kiara  
50480 Kuala Lumpur.

### **Date of revision**

03/08/2022

### **Serial Number**

NPRA (R1/2) 07042022/087  
NPRA (R1/A11) 06122022/014