

# FOSWOMYN 3g Granules For Oral Solution

Fosfomycin Trometamol 5.631g (equivalent to 3g Fosfomycin)

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## **What FOSWOMYN is used for**

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

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

## **How FOSWOMYN works**

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

## **Before you use FOSWOMYN**

### **- When you must not use it**

- If you are hypersensitive to Fosfomycin trometamol or any of the other ingredients in FOSWOMYN.
- The use of FOSWOMYN is not recommended if you have severe kidney problems (creatinine clearance below 10 ml/min).
- Do not use FOSWOMYN in children under 12 years of age.
- FOSWOMYN contains sucrose; it is not recommended if you have rare hereditary problems or fructose intolerance, with glucose-galactose malabsorption or sucrose-isomaltase insufficiency.
- FOSWOMYN should only be used during pregnancy if clearly necessary.
- Do not take FOSWOMYN if you are breastfeeding 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 FOSWOMYN 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 FOSWOMYN.
- anticoagulants, as their ability to prevent your blood from clotting might be altered by Fosfomycin and other antibiotics

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

## **How to use FOSWOMYN**

### **- 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 FOSWOMYN (3g Fosfomycin).

After taking FOSWOMYN, 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 FOSWOMYN (3g fosfomycin) 3 hours prior to the procedure and 1 sachet of FOSWOMYN (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, FOSWOMYN 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 FOSWOMYN can trigger dizziness, this could affect the ability to drive or operate machinery.
- Hypersensitive reactions may occur during treatment with Fosfomycin and maybe life threatening. Do not take FOSWOMYN 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.

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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 FOSWOMYN

### -Storage

Store in its original package.

Do not use if the package is open or torn.

Store below 30°C.

To use immediately after dilution, discard any unused portion.

### -Disposal

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

## Product Description

### - What it looks like?

White or almost white granulate without lumps or particulates

The reconstituted solution is a slightly whitish turbid solution with fruit odour (orange-mandarin).

### - Ingredients

#### - Active ingredient:

Fosfomycin trometamol

#### - Inactive ingredients:

Sucrose, Saccharin Sodium, Mandarin flavour, Orange flavour.

### - MAL Number: -

## Manufacturer

LABIANA PHARMACEUTICALS  
S.L.U.

C/ Casanova 27-31,  
08757 Corbera de Llobregat  
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## Product Registration Holder

Medispec (M) Sdn Bhd  
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