# Monuril® 3g granules for oral solution

(fosfomycin)

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Monuril® 3g granules for oral solution but will be referred to as Monuril throughout the remainder of this leaflet.

## What in this leaflet


1. What Monuril is and what it is used for
2. What you need to know before you take Monuril
3. How to take Monuril
4. Possible side effects
5. How to store Monuril
6. Contents of the pack and other information.


## 1. What Monuril is and what it is used for

Monuril contains the active substance fosfomycin (as fosfomycin trometamol). It is an antibiotic that works by killing bacteria which can cause infections.

Monuril is used to treat uncomplicated infection of the bladder in women and female adolescents.

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

## 2. What you need to know before you take Monuril

### Do not take Monuril if you:

- are allergic to fosfomycin or any of the other ingredients of this medicine (listed in section 6).

### Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Monuril if you suffer from one of the following disorders:
- persistent infections of the bladder,
- previously had diarrhoea after taking any other antibiotics.

Conditions you need to look out for

Monuril can cause serious side effects. These include allergic reactions and an inflammation of the large intestine. You must look out for certain symptoms while you are taking this medicine, to reduce the risk of any problems. See “Serious side effects” in Section 4.

### Children and adolescents

Do not give this medicine to children less than 12 years of age, as its safety and efficacy have not been established in this age group.

### Other medicines and Monuril

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This is especially important if you are taking:
- **metoclopramide** or other medicinal products that increase the movement of food through the stomach and intestines, because they may reduce the uptake of fosfomycin by your body,
- **anticoagulants,** as their ability to prevent your blood from clotting might be altered by fosfomycin and other antibiotics.

### Monuril with food

Food may delay the absorption of fosfomycin. Therefore, this medicinal product should be taken on an empty stomach (2-3 hours before or 2-3 hours after a meal).

### Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are pregnant your doctor will only give you this medicine when it is clearly needed.

Breast-feeding mothers can take a single oral dose of this medicine.

### Driving and using machines

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

### Monuril contains

*Sodium*

This medicine contains less than 1mmol sodium (23mg) per sachet that is to say essentially ‘sodium-free’.

*Sucrose*

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

*Sulphites*

May rarely cause severe hypersensitivity reactions and bronchospasm.

## 3. How to take Monuril

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

In case of treatment of uncomplicated infection of the bladder, in women and female adolescents the recommended dose is 1 sachet of Monuril (3g fosfomycin).

When used as antibiotic prophylaxis for transrectal prostate biopsy the recommended dose is 1 sachet of Monuril (3g fosfomycin) 3 hours prior to the procedure and 1 sachet of Monuril (3g fosfomycin) 24 hours after the procedure.

### Use in patients with renal impairment

This medicine should not be used in patients with severe renal impairment (creatinin clearance < 10ml/min).

### Use in children and adolescents

This medicine should not be used in children less than 12 years of age.

### Method of administration

For oral use.

Take this medicine by mouth, on an empty stomach (2-3 hours before or 2-3 hours after a meal), preferably before going to bed after emptying the bladder.

Dissolve the content of one sachet in a glass of water and drink immediately.

### If you take more Monuril than you should

If you accidentally take more than your prescribed dose, contact your doctor or pharmacist.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

### Serious side effects

**While taking Monuril, if you develop any of the following symptoms you should stop taking the medicine and contact your doctor immediately:**

- anaphylactic shock, a life threatening type of allergic reaction *(the frequency is unknown)*. Symptoms include a sudden onset of rash, itching or hives on the skin and or shortness of breath, wheezing or difficulty in breathing,
- swelling of the face, lips, tongue or throat with breathing difficulties (angioedema) *(the frequency is unknown),*
- moderate to severe diarrhea, abdominal cramps, bloody stools and/or fever may mean 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 (antiperistaltics).

### Other side effects

Common (may affect up to 1 in 10 people):

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

Uncommon (may affect up to 1 in 100 people):

- vomiting
- rash
- urticaria
- itching

Not known (frequency cannot be estimated from the available data):

- allergic reactions.

### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Monuril

**Keep out of the sight and reach of children.**

Store in the original packaging. Store away from direct sunlight.

Do not use the granules after the expiry date which is stated on the carton and sachet labels after 'Exp'. The expiry date refers to the last day of that month.
If the granules become discoloured or show any signs of deterioration, seek the advice of your pharmacist.

Remember if your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.

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.

## 6. Contents of the pack and other information

### What Monuril contains

The active ingredient is fosfomycin. Each sachet contains 5.631g fosfomycin trometamol equivalent to 3g fosfomycin. In total each sachet contains 8g of granules

The other ingredients are saccharin, sucrose, orange flavour (contains maize starch and sulphites (E220 and E222)) and mandarin flavour (contains sucrose and sulphites (E220 and E222)).

### What Monuril looks like and contents of the pack

Monuril is available as white to off-white granules for oral solution, with a characteristic orange odour in a single dose sachet.
Each pack contains 1 sachet.

**Manufactured by:** Zambon, S.p.A. Via della Chimica, 9, 36100 Vicenza, Italy.

**Procured from within the EU and repackaged by the Product Licence holder:** Smartway Pharmaceuticals Limited, 10 Lyon Road, London, SW19 2RL, UK.

**Monuril® 3g granules for oral solution;**

**PL 42332/0042**

**POM**

Leaflet date: 25.04.2023

Monuril® is a trademark of Zambon S.p.A., Italy.

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PACKAGE LEAFLET: INFORMATION FOR THE USER

# Fosfomycin 3g granules for oral solution

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The name of your medicine is Fosfomycin® 3g granules for oral solution but will be referred to as Fosfomycin throughout the remainder of this leaflet.

## What in this leaflet


1. What Fosfomycin is and what it is used for
2. What you need to know before you take Fosfomycin
3. How to take Fosfomycin
4. Possible side effects
5. How to store Fosfomycin
6. Contents of the pack and other information.


## 1. What Fosfomycin is and what it is used for

Fosfomycin contains the active substance fosfomycin (as fosfomycin trometamol). It is an antibiotic that works by killing bacteria which can cause infections.

Fosfomycin is used to treat uncomplicated infection of the bladder in women and female adolescents.

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

## 2. What you need to know before you take Fosfomycin

### Do not take Fosfomycin if you:

- are allergic to Fosfomycin or any of the other ingredients of this medicine (listed in section 6).

### Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Fosfomycin if you suffer from one of the following disorders:
- persistent infections of the bladder,
- previously had diarrhoea after taking any other antibiotics.

Conditions you need to look out for

Fosfomycin can cause serious side effects. These include allergic reactions and an inflammation of the large intestine. You must look out for certain symptoms while you are taking this medicine, to reduce the risk of any problems. See “Serious side effects” in Section 4.

### Children and adolescents

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