PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Fosfomycin 3 g granules for oral solution

fosfomycin trometamol

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.

What is 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

This medicine 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 infections of the bladder in women and adolescent females.

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 taking 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
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 Fosfomycin
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 medicines 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.

Fosfomycin 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.

Fosfomycin contains sucrose and sodium
Fosfomycin contains 2.2 g of sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
This medicine contains less than 1 mmol sodium (23 mg) per sachet, that is to say essentially 'sodium-free'.

3. HOW TO TAKE FOSFOMYCIN

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 (over 12 years of age) the recommended dose is 1 sachet of Fosfomycin (3 g Fosfomycin).

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

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 into a glass of water. The solution may be stirred if necessary. Drink immediately.

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

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

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

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ARTWORK SPECIFICATION		FONTS	COLOURS	DESIGNED BY
Client :	Consilient Health Ltd.	Myriad Pro	Black	Minty
Project :	Dec 2024			VERSION
Item(s) :	Fosfomycin 3 g granules for oral solution			04 (06/01/2025)
Size :	190 x 265 mm			
Software :	InDesign CC			

If you have any further questions on the use of this product, 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 Fosfomycin, if you develop any of the following symptoms **you should stop taking this 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)
- **moderate to severe diarrhoea, 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 diarrhoea that inhibit the bowel movements (antiperistaltics).

Other side effects
If any of the following side effects occur, contact your doctor as soon as possible:

Common (may affect up to 1 in 10 people)
- headache
- dizziness
- diarrhoea - if it becomes severe consult your doctor immediately
- nausea (feeling sick)
- 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 (being sick)
- rash
- urticaria (hives)
- 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 Website: 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 FOSFOMYCIN

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the sachet after EXP. The expiry date refers to the last day of that month.

Do not store above 30° C.

The reconstituted solution should be used immediately.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Fosfomycin contains:
- The active substance is fosfomycin. Each sachet contains 5.631 g of fosfomycin trometamol, equivalent to 3 g of fosfomycin
- The other ingredients are: sucrose, sodium saccharin, mandarin flavour (consisting of: maltodextrin, arabic gum, ascorbic acid (E300), butylhydroxyanisole (E320) and flavouring preparations) and orange flavour (consisting of: maltodextrin, arabic gum, and flavouring preparations).

What Fosfomycin looks like and contents of the pack
Fosfomycin are white or almost white granules with fruit flavour (orange-mandarin).
Each pack contains 1 or 2 sachets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Consilient Health Limited,
Floor 3, Block 3, Miesian Plaza,
Dublin 2, D02 Y754, Ireland.

Manufacturer
LABIANA Pharmaceuticals, S.L.U.
C/ Casanova, 27-31
Corbera de Llobregat
Barcelona, 08757,
Spain

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