

Package leaflet: information for the patient

Fosfomycin 3 g Focus, granules for oral solution in sachet
fosfomycin

Read the entire leaflet carefully before you start using this medicine, because it contains important information for you.

Keep this leaflet. You may need to read it again.

Do you have any further questions? Please ask your doctor or pharmacist.

Do not pass this medicine on to others. It may harm them, even if their symptoms are the same as yours.

Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Please contact your doctor or pharmacist.

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1. What is Fosfomycin 3 g Focus and what is it used for?

Fosfomycin 3 g Focus contains the active substance fosfomycin (as fosfomycin trometamol). It is an antibiotic that works by killing bacteria that can cause infections.

Fosfomycin 3 g Focus is used for the treatment of uncomplicated bladder infections in women aged 12 years and older.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

When should you be extra careful with this medicine?

Contact your doctor, pharmacist, or nurse before using this medicine if you have any of the following conditions:

persistent bladder infections

if you have previously had diarrhea after using other antibiotics

What should you pay attention to?

Fosfomycin 3 g Focus can cause serious side effects, such as allergic reactions and inflammation of the colon. You should watch for certain symptoms while using this medicine to reduce the risk of problems. See "Serious side effects" in Section 4.

Children and adolescents up to 18 years

Do not give this medicine to children under 12 years, as the safety and efficacy have not been established in this age group.

Are you taking any other medicines?

Are you taking any other medicines in addition to this one, have you recently done so, or is there a possibility that you will soon take other medicines (this also applies to over-the-counter medicines)? If so, tell your doctor or pharmacist.

This is especially important if you are taking the following medicines:

Metoclopramide or other medicines that speed up the movement of food through the stomach and intestines, as they can reduce the absorption of fosfomycin by your body
Anticoagulants, because fosfomycin and other antibiotics can affect their ability to prevent your blood from clotting.

What to watch out for with food

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

Pregnancy, breastfeeding, and fertility

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor before using this medicine.

If you are pregnant, your doctor will only give you this medicine if it is clearly necessary.

Mothers who are breastfeeding can take a single oral dose of this medicine.

Driving and using machines

You may experience side effects that can affect your ability to drive or operate machinery, such as dizziness.

Fosfomycin 3 g Focus contains sucrose, glucose, and sodium

If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per dose, which means it is essentially 'sodium-free'.

3. How to use this medicine?

Always take this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

For the treatment of uncomplicated bladder infections in women aged 12 years and older, the recommended dosage is 1 sachet of Fosfomycin 3 g Focus (3 g fosfomycin).

Use in patients with impaired kidney function

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

Use in children and adolescents up to 18 years

This medicine should not be given to children under 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 contents of one sachet in a glass of water and drink it immediately.

The reconstituted solution is a whitish cloudy solution with a fruit flavor (orange-mandarin).

Have you taken too much of this medicine?

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

Do you have any other questions about the use of this medicine? Then contact 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

If you experience any of the following symptoms while using Fosfomycin 3 g Focus, you should stop taking the medicine and contact your doctor immediately:

- Anaphylactic shock, a life-threatening type of allergic reaction (frequency not known). Symptoms may include sudden skin rash, itching or hives and/or shortness of breath, wheezing or difficulty breathing.
- Swelling of the face, lips, tongue, or throat with breathing difficulties (angioedema) (frequency not known).
- Moderate to severe diarrhea, abdominal cramps, bloody stools and/or fever may indicate an infection of the colon (antibiotic-associated colitis) (frequency not known). Do not take anti-diarrhea medicines that slow down bowel movements (antiperistaltic agents).

Other side effects

Common (affect less than 1 in 10 users):

headache

dizziness

diarrhea

nausea

digestive problems (indigestion)

abdominal pain

infection of the female genital organs with symptoms such as inflammation, irritation, itching (vulvovaginitis)

Sometimes (affect less than 1 in 100 users):

vomiting

rash
hives
itching

Unknown (frequency cannot be estimated from the available data):
allergic reactions

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Store below 30 °C.

Do not use this medicine after the expiry date. You can find it on the box and sachet after EXP. It includes a month and a year. The last day of that month is the expiry date. Do not dispose of medicines via the sink or toilet. Ask your pharmacist what to do with medicines you no longer use. They will be destroyed responsibly and will not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

- The active substance in this medicine is fosfomycin (as fosfomycin trometamol). Each sachet with a single dose contains fosfomycin trometamol equivalent to 3 g fosfomycin.
- The other substances in this medicine are: sucrose, sodium saccharin (E954), mandarin flavor (contains glucose from corn maltodextrin and sodium), orange flavor (contains glucose from corn maltodextrin and sodium). See section 2. Fosfomycin 3 g Focus contains sucrose, glucose, and sodium.

What does Fosfomycin 3 g Focus look like and how much is in a package?

Granulate for drink in sachet. White or almost white granules without lumps or particles in a single-dose sachet.

Each package contains 1 or 2 sachets.

Not all mentioned pack sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder
Focus Care Pharmaceuticals B.V.
Westzijde 416

1506 GM Zaandam

Manufacturer

Labiana Pharmaceuticals, S.L.U.
C/ Casanova 27-31
08757 Corbera de Llobregat (Barcelona)
Spain

Registered under:

RVG 124189

This medicine is registered in EEA member states under the following names:

Denmark:	Cystifos
Germany:	Afosfol 3 g Granulate in sachet for preparation of an oral solution
France:	Fosfomycin Zydus 3 g, granules for oral solution in sachet
Hungary:	Afosfol 3 g granules for oral solution
Netherlands:	Fosfomycin 3 g Focus, granules for oral solution in sachet
Poland:	Uromaste
Portugal:	Fosfomycin Pharmakern
Spain:	Fosfomycin Labiana 3 g granules for oral solution in sachets EFG
Sweden:	Cystifos

This leaflet was last approved in August 2022