

PACKAGE LEAFLET: INFORMATION FOR THE USER

Alexi® 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4

What is in this leaflet:

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

1 WHAT ALEXI® 3G GRANULES FOR ORAL SOLUTION IS AND WHAT IT IS USED FOR

Alexi® 3g granules for oral solution belongs to a group of medicines known as antibiotics. It contains the active substance fosfomycin (as fosfomycin trometamol). It works by killing bacteria, which can cause infections.

Fosfomycin is used to treat infections of the bladder (cystitis) in women and female adolescents.

Fosfomycin is also used to prevent possible infections before surgical procedures of the prostate in adult men.

Fosfomycin should not be given to children less than 12 years of age.

2 WHAT YOU NEED TO KNOW BEFORE YOU TAKE ALEXI® 3G GRANULES FOR ORAL SOLUTION

Do not use Alexi® 3g granules for oral solution:

- 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 Alexi® 3g granules for oral solution:

- if you have persistent infections of the bladder
- if you have diarrhoea, or have previously experienced diarrhoea upon administration of any other antibiotics.
- if you are male and you have a history of recurrent urinary infections
- if you have an intolerance to some sugars (see below)

Conditions you need to look out for

Alexi® 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 in children has not been established.

Other medicines and Alexi® 3g granules for oral solution

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 (medicines taken to prevent blood clotting), as their ability to prevent your blood from clotting might be altered by fosfomycin trometamol and other antibiotics.

Alexi® 3g granules for oral solution with food and drink

Food may delay the absorption of fosfomycin. Alexi® 3g granules for oral solution 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.

The effect of fosfomycin on fertility is not known.

Driving and using machines

No studies on the effect on the ability to drive and use machines have been performed.

You may experience side effects such as dizziness which may affect your ability to drive or use machines. Do not drive or use machines if you are affected.

Alexi® 3g granules for oral solution contains 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.

This medicine contains less than 1mmol (23mg) of sodium per sachet and is considered to be "sodium free"

3. HOW TO TAKE ALEXI® 3G GRANULES FOR ORAL SOLUTION

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 infection of the bladder, in women and female adolescents the recommended dose is one sachet (3g) of Alexi® 3g granules for oral solution as a single dose.

When used as antibiotic prophylaxis for transrectal prostate biopsy the recommended dose is 1 sachet of Alexi® 3g granules for oral solution, 3 hours before surgery and 1 sachet of 3g 24 hours after surgery.

Use in children and adolescents

Alexi® 3g granules for oral solution 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 (about 2-3 hours before or 2-3 hours after a meal), preferably before going to bed after emptying the bladder.

The contents of the sachet should be dissolved in a glass of 50 - 75ml drinking water. Stir if necessary to obtain an opalescent solution. Take immediately after preparation of the solution.

If you take more Alexi® 3g granules for oral solution than you should

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

If you forget to take Alexi® 3g granules for oral solution

If you forget to take a dose, take one as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you stop taking Alexi® 3g granules for oral solution This medicine is only taken once.

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

4. POSSIBLE SIDE EFFECTS

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

Serious side effects

Whilst taking Alexi® 3g granules for oral solution, if you develop any of the following symptoms **you should 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 abdominal cramps, bloody stools, diarrhoea 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 to prevent diarrhoea that inhibit your bowel movements (antiperistalsis).

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
- 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
- pruritus (itching)

Unknown frequency

- allergic reactions

Reporting of side effects

If you get any side effects, talk to your doctor, or pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the UK Yellow Card Scheme (website: www.mhra.gov.uk/yellowcard), or search for "MHRA Yellow Card" in 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 ALEXI® 3G GRANULES FOR ORAL SOLUTION

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 after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Alexi® 3g granules for oral solution contains

The active substance is Fosfomycin trometamol. Each sachet contains 5631 mg Fosfomycin trometamol, equivalent to 3.000 g fosfomycin.

The other ingredients are:

Orange flavour (consisting of maltodextrin, dextrose monohydrate, acacia (E414), butylhydroxyanisole (E 320)); natural orange essential oil and natural lemon essential oil (consisting of linalol, ethyl butyrate, ethyl hexanoate, isoamyl hexanoate, natural citral 96%, isoamyl acetate and nerol); Saccharin sodium, Sucrose.

What Alexi® 3g granules for oral solution looks like and contents of the pack

White, off-white granules in a single-dose sachet.

Alexi 3g® granules for oral solution is available in packs of:

Paper/LDPE/Alu/LDPE sachet
1 sachet of 8g (3g of fosfomycin),
2 sachets each of 8g (3g of fosfomycin).
Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Parapharm Development Limited,
Building 1410, Arlington Business Park, Theale,
Reading, RG7 4SA, United Kingdom

Manufacturer

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