

Approved Patient Information Leaflet for Medicines for Human Use:

FOSFOMYCIN 3 g AUSTELL

SCHEDULING STATUS: S4

FOSFOMYCIN 3 g AUSTELL granules for oral solution

Fosfomycin trometamol

Contains sugar (sucrose: 2,213 g per sachet)

Read all of this leaflet carefully before you start taking FOSFOMYCIN 3 g AUSTELL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- FOSFOMYCIN 3 g AUSTELL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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2. What you need to know before you take FOSFOMYCIN 3 g AUSTELL
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4. Possible side effects
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1. What FOSFOMYCIN 3 g AUSTELL is and what it is used for

FOSFOMYCIN 3 g AUSTELL contains fosfomycin trometamol. Fosfomycin trometamol is an antibiotic that works by killing bacteria which can cause infections.

FOSFOMYCIN 3 g AUSTELL is used to treat or prevent uncomplicated bladder infections.

2. What you need to know before you take FOSFOMYCIN 3 g AUSTELL

Do not take FOSFOMYCIN 3 g AUSTELL

- if you are hypersensitive (allergic) to fosfomycin or any of the other ingredients of FOSFOMYCIN 3 g AUSTELL (listed in section 6)
- if you have severe kidney problems (creatinine clearance below 10 mL/min)
- are undergoing haemodialysis.

If you are uncertain whether any of these apply to you, please discuss this with your doctor or pharmacist before taking FOSFOMYCIN 3 g AUSTELL.

Warnings and precautions

Tell your doctor or healthcare professional before taking FOSFOMYCIN 3 g AUSTELL if you:

- have previously had diarrhoea after taking any other antibiotics
- have kidney problems, but your creatinine clearance is above 10 mL/min.

Children

Do not give FOSFOMYCIN 3 g AUSTELL to children under 12 years.

Other medicines and FOSFOMYCIN 3 g AUSTELL

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

If you are taking any medicines containing the following:

- metoclopramide (used to treat nausea and vomiting) or other medicines that increase the movement of food through the stomach and intestines as the uptake of fosfomycin by your body may be decreased
- anticoagulants such as warfarin (used to “thin” your blood) as your clotting time may be affected.

Consult your doctor, pharmacist or other healthcare professional as these medicines may interact with FOSFOMYCIN 3 g AUSTELL.

FOSFOMYCIN 3 g AUSTELL with food and drink

FOSFOMYCIN 3 g AUSTELL should be dissolved in water and taken at least two hours prior to the next meal. Food delays and reduces absorption of fosfomycin.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Do not take FOSFOMYCIN 3 g AUSTELL if you are pregnant or breastfeeding.

There are no known effects of fosfomycin trometamol on fertility.

Driving and using machines

FOSFOMYCIN 3 g AUSTELL can cause dizziness. Do not drive or operate machinery until you know how FOSFOMYCIN 3 g AUSTELL affects you.

FOSFOMYCIN 3 g AUSTELL contains sucrose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking FOSFOMYCIN 3 g AUSTELL.

3. How to take FOSFOMYCIN 3 g AUSTELL

Do not share medicines prescribed for you with any other person.

Always take FOSFOMYCIN 3 g AUSTELL exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

- for women (up to seventy-five years of age) with an uncomplicated urinary tract infection, such as a bladder infection: a single 3 g dose is recommended.
- for adult men (including the elderly) needing prophylaxis (prevention of a possible infection) before transurethral surgical and diagnostic procedures: two doses of 3 g are recommended. The first dose should be taken three hours before surgery. The second dose should be taken twenty-four hours after surgery.

If you have the impression that FOSFOMYCIN 3 g AUSTELL is too strong or too weak, tell your doctor or pharmacist.

Method of administration

Dissolve the contents of one sachet of FOSFOMYCIN 3 g AUSTELL in a glass of water and drink immediately.

Take FOSFOMYCIN 3 g AUSTELL at least two hours prior to the next meal.

If you take more FOSFOMYCIN 3 g AUSTELL than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take FOSFOMYCIN 3 g AUSTELL

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.

4. Possible side effects

FOSFOMYCIN 3 g AUSTELL can have side effects.

Not all side effects reported for FOSFOMYCIN 3 g AUSTELL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FOSFOMYCIN 3 g AUSTELL, please consult your health care provider for advice.

If any of the following happens, stop taking FOSFOMYCIN 3 g AUSTELL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- difficulty breathing, chest pain or chest tightness, and/or feeling dizzy/faint, severe itching of the skin or raised lumps on the skin, swelling of the face, lips, tongue and /or throat, which may cause difficulty in swallowing, collapse.

These are very serious side effects. If you have them, you may have had a serious reaction to FOSFOMYCIN 3 g AUSTELL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- mild to severe abdominal cramps, bloody stools, diarrhoea and/or fever, this may mean you have an infection of the large intestine (antibiotic-associated colitis).

This is a serious side effect. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent:

- infection of the female genital organs with symptoms like inflammation, irritation, itching (vulvovaginitis)
- headache, dizziness
- abdominal pain (pain in the stomach area)
- heartburn, indigestion
- sore throat
- runny or stuffy nose
- back pain
- painful menstruation
- pain, unusual tiredness or weakness
- skin rash

Less frequent:

- vomiting
- hives, itchy skin.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of FOSFOMYCIN 3 g AUSTELL.

5. How to store FOSFOMYCIN 3 g AUSTELL

- Store all medicines out of reach of children.
- Store in the original packaging until required for use.
- Store at or below 25 °C.
- Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What FOSFOMYCIN 3 g AUSTELL contains

- The active substance is fosfomycin. Each sachet contains 5,631 g of fosfomycin trometamol equivalent to 3,0 g fosfomycin.
- The other ingredients are mandarin flavour, orange flavour, sodium saccharin, sucrose (see section 2 for information on sucrose).

What FOSFOMYCIN 3 g AUSTELL looks like and contents of the pack

FOSFOMYCIN 3 g AUSTELL granules are packed in sachets composed of surlyn/ aluminium/ low-density polyethylene/ paper. Each sachet contains white or almost white granules.

One or two sachets are packed in a cardboard box.

Not all pack sizes may be marketed.

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