Patient Information Leaflet for SUNFOZ

SCHEDULING STATUS

S4

SUNFOZ 3 g granules for oral solution

Fosfomycin

Contains sugar: 2 153 mg sucrose per sachet.

Contains sweetener: 16 mg saccharin sodium per sachet.

Read all of this leaflet carefully before you start taking SUNFOZ:

- 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.
- SUNFOZ 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:

1. What SUNFOZ is and what it is used for

SUNFOZ contains the active substance fosfomycin. Fosfomycin is an antibiotic that works by killing bacteria that can cause infections.

SUNFOZ is used:

- To treat or prevent uncomplicated infections of the bladder in female patients 12 years and older.
- To prevent bladder infection in men after certain surgical or diagnostic transurethral procedures.

SUNFOZ is not suitable for the treatment of children younger than 12 years of age.

2. What you need to know before you take SUNFOZ

Do not take SUNFOZ if you:

- Are hypersensitive (allergic) to fosfomycin or any of the other ingredients of SUNFOZ (listed in section 6 of this leaflet).
- Have severe kidney problems (creatinine clearance below 10 mL/min).
- Are undergoing haemodialysis.

Warnings and precautions:

Take special care with SUNFOZ if you have:

- Persistent infections of the bladder.
- Previously had diarrhoea after taking any other antibiotics. Tell your doctor, as you may develop serious diarrhoea during or after using SUNFOZ, and this needs to be treated immediately (also see section 4).

Children and adolescents:

Do not give SUNFOZ to children younger than 12 years of age.

Other medicines and SUNFOZ:

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

Tell your doctor or pharmacist if you are using:

- Metoclopramide or other medicines that increase the movement of food through the stomach and intestines.
- Anticoagulants as their ability to prevent your blood from clotting might be altered by fosfomycin.

SUNFOZ with food and drink:

Food may delay the absorption of fosfomycin. Therefore, SUNFOZ should be taken on an empty stomach at least 2 hours before or 2 to 3 hours after a meal.

Pregnancy and breastfeeding:

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 SUNFOZ.

You should not breastfeed while you are taking SUNFOZ.

Driving and using machines:

You may feel dizzy or tired when taking SUNFOZ, which may affect your ability to drive or use machines. Do not drive or use machines until you know you SUNFOZ affects you.

It is not always possible to predict to what extent SUNFOZ may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SUNFOZ affects them.

SUNFOZ contains sucrose:

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

3. How to take SUNFOZ

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

Always take SUNFOZ exactly as your doctor has told you. Check with your doctor if you are not sure.

The usual dose is:

- For bladder infection in female patients over 12 years of age, take one sachet of SUNFOZ, once as a single dose.
- For prevention of infection in men after surgical or diagnostic transurethral procedures, take one sachet of SUNFOZ 3 hours before the procedure and one sachet of SUNFOZ 24 hours after the procedure.

The contents of one sachet should be dissolved in a glass of water and taken immediately after its preparation.

If you have the impression that the effect of SUNFOZ is to strong or too weak, tell your doctor or pharmacist.

If you take more SUNFOZ than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is

available, contact the nearest hospital or poison centre.

You may experience loss of balance, difficulty hearing or changes in the way you taste things. Your doctor will treat this as necessary.

If you forget to take SUNFOZ:

Do not take a double dose to make up for a forgotten dose. If you miss a dose of SUNFOZ take it as soon as you remember.

4. Possible side effects

SUNFOZ can have side effects.

Not all side effects reported for SUNFOZ are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SUNFOZ, please consult your doctor, pharmacist or other health care provider for advice.

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

- Anaphylactic shock, a very serious allergic reaction. Symptoms include a sudden onset of rash, ithcing or hives on the skin and/or shortness of breath, wheezing or difficulty breathing.
- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.

These are all very serious side effects. If you have them, you may have had a serious reaction to SUNFOZ. 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:

- Moderate to severe diarrhoea, abdominal cramps, bloody stools and/or fever. This may mean that you have an infection of the large intestine (antibiotic-associated colitis). Do not take medicines against diarrhoea that inhibit the bowel movements.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- Infection of the female genital organs with symptoms like inflammation, irritation, itching (vulvovaginitis).
- Headache, dizziness.
- Sore throat (pharyngitis), runny or stuffy nose (rhinitis).
- Nausea, heartburn, indigestion, abdominal pain.
- Inflammation of the vagina that can result in discharge, itching and pain (vaginitis).
- Painful menstrual periods.
- Back pain.
- Abnormal weakness or lack of energy.
- Generalised pain.

Less frequent side effects:

- Vomiting.

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 or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of SUNFOZ. *Suspected adverse reactions can also be reported directly to the Holder of certificate of registration via email or telephonically: pharmacovigilance.africasme@sunpharma.com or tel: +27 (0) 12 643 2000*

5. How to store SUNFOZ

- Store at or below 25 °C
- Keep in the original container.
- The reconsistuted solution should be taken immediately.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What SUNFOZ contains:

The active ingredient is fosfomycin.

Each single dose sachet contains 3,0 g fosfomycin (as fosfomycin trometamol).

The other ingredients are: sucrose, saccharin sodium, natural orange flavouring 87D645 (containing maltodextrin, arabic gum, citric acid, sodium citrate, butylated hydroxyanisole) and natural mandarin flavouring WONF 87D646 (containing maltodextrin, arabic gum, citric acid, sodium citrate).

What SUNFOZ looks like and contents of the pack:

Almost white mixture of powder and granules with citrus flavour.

Three-layer polyethylene-aluminium-paper sachet supplied in an outer

carton containing 1 sachet each.

Holder of certificate of registration:

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road

Stormill, Ext 1

Roodepoort, 1724

South Africa

Tel: +27 (0) 12 643 2013

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Access to the corresponding PIL translation: The PIL is available in one other language (Afrikaans), a copy is accessible on the company website: https://sunpharma.com/south-africa-products/

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