PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

UROSEPTIC 3 g granules for oral solution
Fosfomycin
Contains sweetener (sucralose,0,113 g per sachet)

Read all of this leaflet carefully before you start taking UROSEPTIC.
- 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.
- UROSEPTIC 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 UROSEPTIC is and what it is used for
2. What you need to know before you take UROSEPTIC
3. How to take UROSEPTIC
4. Possible side effects
5. How to store UROSEPTIC
6. Contents of the pack and other information

1. What UROSEPTIC is and what it is used for
UROSEPTIC contains the active substance fosfomycin (as fosfomycin trometamol). It is an antibiotic that works by killing bacteria which can cause infections.

UROSEPTIC is used to treat uncomplicated infection of the bladder in women over 12 years of age.

UROSEPTIC is used as antibiotic prophylaxis for transrectal prostate biopsy in adult men.

2. What you need to know before you take UROSEPTIC
Do not take UROSEPTIC:
- If you are hypersensitive (allergic) to fosfomycin or any of the other ingredients of UROSEPTIC (see section 6).
- If you have severe kidney problems.

Warnings and Precautions
Take special care with UROSEPTIC:
- Stop using UROSEPTIC if you experience any symptoms of an allergic reaction. If such a reaction occurs, you should never use UROSEPTIC again.
- If you have severe and persistent diarrhoea during or after treatment with UROSEPTIC contact your doctor immediately. If you are diagnosed with pseudo-membranous colitis, your doctor will treat you appropriately.
- If you have persistent infections of the bladder. Your doctor will have to re-evaluate your condition.

Children and adolescents
Safety and efficacy in children under the age of 12 years have not yet been established.

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

Tell your doctor if you are taking, have recently taken or might take any of the following medicines:
- Metoclopramide or other medicines that increase the movement of food through the stomach and intestines, because they may reduce the uptake of UROSEPTIC by your body.

- Anticoagulants, as their ability to prevent your blood from clotting might be altered by UROSEPTIC and other antibiotics.

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 healthcare provider for advice before taking UROSEPTIC.

Breastfeeding
Do not use UROSEPTIC if you are breastfeeding.

Fertility
There are no known effects of fosfomycin on fertility.

Driving and using machines
UROSEPTIC may cause you to experience side effects, such as dizziness, which may affect your ability to drive or use machines. Take special care before performing tasks requiring your attention, until you know how UROSEPTIC will affect you.

3. How to take UROSEPTIC

Do not share medicines prescribed for you with any other person. Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

You should take UROSEPTIC at least 2 hours prior to your next meal.
The contents of the sachet should be dissolved in half a glass of water and taken immediately.

Adults (including elderly patients up to 75 years):
To treat bladder infections in women (12 years and over):
One sachet (3 g) as a single dose.

To prevent bladder infections in men:
Two sachets (2 x 3 g) as two individual doses.
The first dose should be taken 3 hours before surgery. The second dose should be taken 24 hours after surgery.

Instructions for reconstitution:
Pour the content of one sachet into half a glass of water.
The solution should be taken immediately after being prepared.

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

If you take more UROSEPTIC than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take UROSEPTIC
If you forget to take UROSEPTIC, take a dose as soon as you remember, then continue to take UROSEPTIC at the usual times. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

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

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

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Pain or inflammation of the joints, unusual bruising, skin eruptions and swelling, skin sensitivity to the sun, fever, flushing, feeling unwell.

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

Tell your doctor if you notice any of the following:
Frequent side effects:
- Infection of the female genital organs (vulvovaginitis) characterised by inflammation, irritation, itching.
- Headache, dizziness.
- Sore throat, runny or stuffy nose.
- Diarrhoea, nausea, stomach pain, heartburn, indigestion.
- Skin rash.
- Back pain.
- Vaginal inflammation, painful menstrual periods.
- General pain, unusual weakness or tiredness.

Less frequent side effects:
- Vomiting.
- Hives, itching.

Frequency unknown:
- Inflammation of the large intestine caused by the use of antibiotics.
- Swelling under the skin (angioedema).

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 "**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 UROSEPTIC.

5. How to store UROSEPTIC
Store all medicines out of reach of children.
Store at or below 30 ºC.
Store in the original packaging.
Do not take after the expiry date stated on the package.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What UROSEPTIC contains
The active substance is fosfomycin trometamol equivalent to 3 g fosfomycin base.

The other ingredients are aerosil 380, glycine, lemon flavour, povidone and sucralose.

What UROSEPTIC looks like and contents of the pack
Sachets containing white to off-white, homogeneous granules.

Aluminium foil, externally covered by paper featured as a dull, smooth surface, and internally seen as a brilliant surface. Sachets are packed into cardboard boxes with the leaflet.

Pack size: 1, 2 or 10 sachets per carton.
Not all pack sizes may be marketed.

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