SCHEDULING STATUS
S4

URIZONE 3 g, granules
Fosfomycin trometamol
Contains sugar: 2,213 g sucrose per sachet.
Contains sweetener: 0,016 g saccharin per sachet.

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

1. What URIZONE 3 g is and what it is used for
URIZONE 3 g is a broad-spectrum bactericidal antibiotic.
URIZONE 3 g is used to treat urinary tract infections such as bladder infections in women and female adolescents over the age of twelve years.
URIZONE 3 g is used to prevent infections in men undergoing urinary surgical procedures.

2. What you need to know before you take URIZONE 3 g
Do not take URIZONE 3 g:
- if you are hypersensitive (allergic) to fosfomycin trometamol or any of the other ingredients of URIZONE 3 g (listed in section 6).
- if you have kidney disease: The effects of fosfomycin may be increased because of slower removal from the body.

Warnings and precautions
Take special care with URIZONE 3 g:
- When you experience any allergic type reactions (as certain allergic reactions may be fatal). You should stop treatment with URIZONE 3 g, and you should go to your nearest hospital.
- If you have diarrhoea or if you previously had diarrhoea after taking antibiotics.
- If you have persistent bladder infections, especially if you are male, your doctor may need to check for more serious infections before using URIZONE 3 g.

Children
Safety and efficacy in children under the age of twelve years has not yet been established.

Other medicines and URIZONE 3 g
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)
- Tell your doctor if you are taking metoclopramide (used to treat nausea (feeling sick) and vomiting (being sick)).
- If you are taking anticoagulants, as their ability to prevent your blood from clotting might be altered by fosfomycin and other antibiotics.

URIZONE 3 g with food and drink
Food may delay the absorption of URIZONE 3 g. Therefore, URIZONE 3 g should be taken on an empty stomach (2-3 hours before or 2-3 hours after a meal).

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 URIZONE 3 g.

Small amounts of this medicine may pass into the breast milk and may affect the baby. Therefore, your doctor will decide whether you should take URIZONE 3 g while breast-feeding.
There is no information available on the impact of URIZONE 3 g on fertility.

Driving and using machines
URIZONE 3 g may cause dizziness which can affect your ability to drive a vehicle and use machines. It is not always possible to predict to what extent URIZONE 3 g may interfere with your daily activities. Do not engage in the above activities until you know how URIZONE 3 G affects you.

URIZONE 3 g contains sucrose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking URIZONE 3 g.

3. How to take URIZONE 3 g
Do not share medicines prescribed for you with any other person. Always take URIZONE 3 g exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose for uncomplicated urinary tract infections in women and female adolescents over the age of twelve years and women up to the age of seventy-five years, is a single 3 g dose.
The recommended dose to prevent a bacterial infection before a urinary surgical procedure in adult men, including the elderly, is two doses of 3 g. The first dose should be taken three hours before surgery. The second dose should be taken twenty-four hours after surgery.

Dissolve URIZONE 3 g in a glass containing 90–120 mL of water and drink it as soon as it has been dissolved.

Take URIZONE 3 g on an empty stomach (2-3 hours before or 2-3 hours after a meal), preferably before going to bed after emptying the bladder.

If you have the impression that the effect of URIZONE 3 g is too strong or too weak, tell your doctor or pharmacist.

If you take more URIZONE 3 g than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,

- rash or itching,
- fainting.

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

Tell your doctor if you notice any of the following:

- headache, dizziness,
- sore throat, runny or stuff nose,
- diarrhoea, nausea (feeling sick),
- stomach pain, heartburn,
- skin rash, hives, itching
- back pain,
- vaginal discharge,
- vaginal redness, itching, irritation, burning,
- painful periods (menstruation)
- pain, weakness,
- allergic reactions,
- vomiting,
- rapid swelling of the area beneath the skin especially of the face, throat, hands, feet and genitals.

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 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 URIZONE 3 g.

You may also report side effects directly to Adcock Ingram Limited by emailing Adcock.aereports@adcock.com.

5. How to store URIZONE 3 g

- Store at or below 30 °C.
- Store in the original packaging until required for use.
- Store all medicines out of reach of children.
- Do not store in a bathroom.
- 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.
- 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 URIZONE 3 g contains

- The active substance is fosfomycin trometamol. Each sachet contains 5,631 g of fosfomycin trometamol, equivalent to 3 g of fosfomycin
- The other ingredients are mandarin flavour, orange flavour, saccharin and sucrose.

What URIZONE 3 g looks like and contents of the pack
White granular powder with a characteristic mandarin flavour.
Printed carboard carton containing one paper-polyethylene-aluminium-polyethylene laminated sachet.

Holder of Certificate of Registration
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