

LABELLING - PATIENT INFORMATION LEAFLET

The under-mentioned information with regard to this medicine shall appear on the patient information leaflet. The information shall be presented in the format stipulated, provided that the Council may authorise any deviation from such information or such format (Refer to Regulation 10 of the Act).

1. Scheduling status
2. Proprietary name and dosage form
3. Composition of the medicine, that is, what this medicine contains
4. Approved indication and use, that is, what this medicine is used for
5. Instruction before taking the medicine (refer to the Guidelines)
6. Instructions on how to take this medicine (refer to Guidelines)
7. Side effects {refer to Guidelines)
8. Storage and disposal information (refer to Guidelines)
9. Presentation
10. Identification
11. Registration number
12. Name and business address of the holder of the certificate of registration
13. Date of publication of the Patient Information Leaflet

Please note that the proposed Patient Information Leaflet is based on the proposed Package Insert. A separate submission of the proposed Patient Information Leaflet has been made to the Clinical Unit for evaluation of the clinical aspects. The proposed patient information leaflet has been included in this MRF1 update for assessment of the pharmaceutical aspects thereof.

**Please read this leaflet carefully before you start taking this medicine.
Keep this leaflet. You may need to read it again.
If you have further questions, please ask your doctor or your pharmacist.
This medicine 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.**

SCHEDULING STATUS: S4

PROPRIETARY NAME AND DOSAGE FORM: URIZONE 2g and 3g (Granules)

Fosfomycin trometamol equivalent to 2g or 3g of Fosfomycin base.

1. WHAT URIZONE CONTAINS:

This medicine contains the active ingredient fosfomycin trometamol.

URIZONE 2g:

Each sachet contains 3,754g fosfomycin trometamol equivalent to fosfomycin 2g.

Contains sugar. 2,100 g sucrose per sachet.

URIZONE 3g:

Each sachet contains 5,631 g fosfomycin trometamol equivalent to fosfomycin 3g.

Contains sugar. 2,213 g sucrose per sachet

The other ingredients are saccharin, mandarin flavour, orange flavour and purified water.

2. WHAT URIZONE IS USED FOR:

a. Pharmacotherapeutic group:

URIZONE is a broad-spectrum bactericidal antibiotic.

b. Therapeutic indication:

URIZONE is used to treat urinary tract infection and cystitis (bladder infection) in women, men and female children over the age of five years.

This medicine is available only with a doctor's prescription.

BEFORE TAKING URIZONE:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **URIZONE** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional, for advice.

If you are pregnant or breast feeding your baby, while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

a. Do not use this medicine:

If you had ever had any unusual or allergic reaction to fosfomicin or any of the other ingredients of **URIZONE**.

b. Take special care with URIZONE:

If you have other medical problems, this may affect the way in which **URIZONE** should be used.

Make sure you tell your doctor if you have any other medical problems, especially:

- Kidney disease: The effects of fosfomicin may be increased because of slower removal from the body.

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

Precautions while using this medicine:

It is important that you check with your doctor if your symptoms do not improve within 2 or 3 days or if they become worse.

c. Taking URIZONE with food and drink:

URIZONE is administered orally after reconstitution in water. To be taken at least two hours prior to the next meal.

Food delays and reduces absorption of fosfomycin trometamol, resulting in reduced blood and urinary concentrations.

d. Pregnancy and breast-feeding:

Do not take **URIZONE** while you are pregnant or breast-feeding.

- **Pregnancy** - If you are pregnant or breast-feeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice. Studies with **URIZONE** in pregnant women have not been done.
- **Breast-feeding** - **URIZONE** is distributed into human breast milk. Use by nursing mothers is not recommended and mothers should be advised to contact a doctor before nursing.

e. Driving and using machinery:

The ability to drive or operate machinery is not affected by the use of **URIZONE**.

f. Taking other medicines with URIZONE:

If you are taking medicines on a regular basis, including complementary or traditional medicines, the use of

URIZONE with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice. When you are taking fosfomycin, it is especially important that your healthcare professional knows if you are taking metoclopramide. Taking **URIZONE** and metoclopramide at the same time, has been shown to lower blood and urinary concentrations and should therefore be avoided.

4. INSTRUCTIONS ON HOW TO TAKE URIZONE:

UR/ZONE must be dissolved in water before it is taken. Take the medicine as soon as it has dissolved. To be taken at least two hours before the next meal.

The recommended dose for uncomplicated urinary tract infections in women, including the elderly up to seventy-five years, is a single 3g dose.

Female children over the age of five years should be given a single 2g dose.

The recommended dose for prevention of a bacterial infection before a transurethral surgical and diagnostic procedure in adult men, including the elderly, is two doses of 3g. The first dose should be taken three hours before surgery. The second dose should be taken twenty-four hours after surgery.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center. Urinary elimination of the medicine can be accelerated through adequate administration of oral fluids.

Treatment is primarily supportive and symptomatic.

5. POSSIBLE SIDE EFFECTS:

URIZONE can have side effects.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen, while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Check with your doctor immediately if any of the following side effects occur:

More common: Vaginal discharge and painful periods (menstruation).

Other side effects may occur that usually do not need medical attention. However, if any of the following side effects continue or are bothersome, check with your doctor.

More common: Diarrhoea, headache and nausea.

Less common: Abdominal or stomach pain; back pain; dizziness; heartburn; indigestion; generalized pain; painful menstruation; runny or stuffy nose; skin rash; sore throat; weakness

6. STORAGE AND DISPOSING OF URIZONE:

Keep all medicines out of the reach and sight of children.

Store in the original package below 25 °C in a dry place.

PRESENTATION:

Carton containing one sachet.

IDENTIFICATION:

Each sachet contains white granular powder which has a characteristic citrus odour.

REGISTRATION NUMBER:

URIZONE 2g: 28/20.1.1/0479

URIZONE 3g: 28/20.1.1/0480

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF
REGISTRATION:**

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