

**SCHEDULING STATUS:** **S4**

**PROPRIETARY NAME:** **URIZONE 2 g and 3 g Granules**

**(AND DOSAGE FORM):** **Granules**

**COMPOSITION:**

**URIZONE 2 g:**

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

Contains sugar: 2,100 g sucrose per sachet.

**URIZONE 3 g:**

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

Contains sugar: 2,213 g sucrose per sachet.

**PHARMACOLOGICAL CLASSIFICATION:**

A.20.1.1 Broad & Medium Spectrum Antibiotics

**PHARMACOLOGICAL ACTION:**

Fosfomycin trometamol is a broad-spectrum bactericidal antibiotic, derived from phosphonic acid with activity in the lower urinary tract.

The antibacterial activity of fosfomycin is due to an inhibition of bacterial cell wall synthesis. Its particular mechanism of action is inhibition of enol pyruvyl transferase.

Fosfomycin is active *in vitro* against species of Gram-positive and Gram-negative bacteria most frequently isolated in urinary tract infections (E. Coli, Proteus, Klebsiella, Enterobacter, Staphylococcus, Streptococcus). In vitro sensitivity does not necessarily imply *in vivo* efficacy.

Fosfomycin trometamol is an orally well-absorbed salt of fosfomycin. It usually provides therapeutic concentrations of the active moiety in the urine for periods of thirty-six hours or more from a single dose.

Fosfomycin is eliminated mainly unchanged through the kidneys and this results in very high peak urinary concentrations (approx. 3000 mg/l) within two to four hours.

Therapeutic concentrations in urine are usually maintained for at least thirty-six hours.

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

In patients with moderately reduced renal function (creatinine clearance > 80 ml/min), including the physiological reduction in the elderly, the half-life of fosfomycin is prolonged but urinary concentration remains therapeutically adequate.

#### **INDICATIONS:**

**URIZONE** is indicated as a single dose in the treatment of acute uncomplicated lower urinary tract infections caused by sensitive E Coli, in women and female children over the age of five years.

**URIZONE** is indicated for prophylaxis in diagnostic and surgical transurethral procedures in adult men.

#### **CONTRA-INDICATIONS:**

Known hypersensitivity to fosfomycin trometamol.

Severe renal insufficiency (creatinine clearance < 10 ml/min).

**WARNINGS:**

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

**INTERACTIONS:**

Concomitant administration of metoclopramide has been shown to lower serum and urinary concentrations and should be avoided.

**PREGNANCY AND LACTATION:**

No evidence in animals or humans has been found to indicate adverse effects of **URIZONE** in pregnancy. However, the safety and efficacy of single dose therapy has not been established for **URIZONE** in pregnancy.

**URIZONE** should not be given to lactating women. Fosfomycin has been shown to cross into breast milk.

**DOSAGE AND DIRECTIONS FOR USE:**

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

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

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

The recommended dose for prophylaxis prior to transurethral surgical and diagnostic procedures 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.

#### **SIDE EFFECTS AND SPECIAL PRECAUTIONS:**

**URIZONE** is generally well tolerated.

The following convention is used to define the frequency of side effects: Very common (>1/10); Common (>1/100, <1/10); Uncommon (>1/1000, <1/100); Rare (>1/10 000, <1/1000); Very rare (<1/10 000) including isolated reports.

#### **Reproductive system and breast disorders:**

*Common:* Vaginitis, dysmenorrhoea.

#### **Gastrointestinal disorders:**

*Very common:* Diarrhoea, nausea.

*Common:* Nausea, abdominal pain, dyspepsia (heartburn, indigestion).

#### **Nervous system disorders:**

*Very common:* Headache.

*Common:* Dizziness.

#### **Musculoskeletal and connective tissue disorders:**

*Common:* Back pain.

#### **Respiratory, thoracic and mediastinal disorders:**

*Common:* Pharyngitis (sore throat), rhinitis (runny or stuffy nose).

**Skin and subcutaneous tissue disorders:**

*Common:* Skin rash.

**General disorders and administration site conditions:**

*Common:* Pain (non-localised), asthenia.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS**

**TREATMENT:**

In the event of overdose, urinary elimination of the medicine can be accelerated through adequate administration of oral fluids.

**IDENTIFICATION:**

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

**PRESENTATION:**

Carton containing one sachet.

**STORAGE INSTRUCTIONS:**

Store at room temperature (25 °C).

**KEEP OUT OF REACH OF CHILDREN.**

**REGISTRATION NUMBER:**

URIZONE 2 g: 28/20.1.1/0479

URIZONE 3 g: 28/20.1.1/0480

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

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