# Monurol® 3 g

**Composition**
*Active ingredient:* Fosfomycin 3 g as Fosfomycin trometamol (1:1) 5.631 g.

**Excipients**
Sucrose (2.213 g corresponding to 37 kJ or 0.088 bread units), Saccharin, Flavours, Excipients for each granule sachet 8 g.
Monurol 3g contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.
*Warning for diabetic subjects:* in case of treatment of diabetic subjects, it should be duly considered that each sachet of Monurol contains 2.213 g sucrose, corresponding to 37 kJ or 0.088 bread units.

**Galenic formulation and amount of active ingredient for each pharmaceutical form**
1 granule sachet contains 3 g fosfomycin.

**Indications/Therapeutic use**
Monurol is indicated in the following infections caused by fosfomycin-sensitive germs:
acute, uncomplicated urinary tract infections;
asymptomatic bacteriuria;
prophylaxis of lower urinary tract infections following surgical or diagnostic interventions (e.g. TUR).

**Posology/Method of administration**
***Usual posology***
*Adults:* 1 sachet of Monurol 3 g as single dose.
*Prophylaxis:* 1 sachet of Monurol 3 g about 3 hours before and 24 hours after surgical intervention.
***Correct method of administration***
Monurol should be taken on an empty stomach, namely 2–3 hours before or after meals, preferably in the evening, after bladder emptying.
Monurol should be dissolved into a glass of water or any other non-alcoholic drink and immediately ingested.

**Contraindications**
Ascertained hypersensitivity to fosfomycin or to any of the product excipients.
Kidney failure with creatinine clearance <80 ml/min.
Patients undergoing haemodialysis.

**Special warnings and precautions for use**
Since only a reduced number of studies in children is available – owing to the product dosage - Monurol 3 g use is not appropriate in children and young people with body weight lower than 50 kg. The administration of Monurol to these subjects should be therefore avoided.
Antibiotic associated colitis (incl. pseudomembranous colitis) has been reported in association with the use of broad spectrum antibiotics including fosfomycin trometamol; therefore it is important to consider this diagnosis in patients who develop serious diarrhoea during or after the use of fosfomycin trometamol. In this situation adequate therapeutic measures should be initiated immediately. Drugs inhibiting peristalsis are contraindicated in this situation.

**Interaction with other medicinal products and other forms of interaction**
The concomitant administration of metoclopramide, antacids, calcium salts or other drugs that increase gastrointestinal motility induces a significant reduction in fosfomycin therapeutically effective plasma and urinary concentrations.
Interaction studies have been performed only on adults.
The administration of fosfomycin trometamol during concomitant food intake decreases fosfomycin plasma and urinary levels.

**Pregnancy/Lactation**
***Pregnancy***
The available data relating to a limited number of pregnat women treated with Monurol, evidenced no undesirable effects on pregnancy evolution or foetus or newborn safety.
No epidemiologic studies are available.
Animal studies revealed no direct or indirect toxicity affecting pregnancy and embryonal, foetal and/or postnatal development.
Anyway due caution is required when using the product during pregnancy.
***Lactation***
The available data indicate that Monurol is excreted into the mother's milk, therefore extreme caution is recommended in case of administration during the lactation period.

**Effects on ability to drive and use machines**
There are evidences that Monurol may cause dizziness, thus the reaction capacity, the driving capability and machines use could be affected.

**Undesirable effects**
The most common adverse reactions following the single-dose administration of fosfomycin trometamol involve the gastrointestinal tract, mainly diarrhoea. These events are usually self-limited in duration and resolve spontaneously.
The following table displays ADRs that have been reported with the use of Monurol 3g from either clinical-trial or post-marketing experiences.
The displayed frequency categories use the following convention:
Very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated form the available data)
Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

| **System Organ Class** | **Adverse Drug Reactions Frequency Category** | | | |
|---|---|---|---|---|
| | **Common** (≥ 1/100 to < 1/10) | **Uncommon** (≥ 1/1,000 to < 1/100) | **Rare** (< 1/1000) | **Not Known** |
| Infections and infestations | Vulvovaginitis | | | |
| Immune system disorders | | | | Anaphylactic shock, Allergic reaction |
| Nervous system disorders | Headache, Dizziness | Paraesthesia | | |
| Cardiac disorders | | | Tachycardia | |
| Respiratory, thoracic and mediastinal disorders | | | | Asthma |
| Gastrointestinal disorders | Diarrhoea, Nausea, Dyspepsia | Abdominal pain, Vomiting | | Psudomembranous colitis |
| Skin and subcutaneous tissue disorders | | Rash, Urticaria, Pruritus | | Angioedema |
| General disorders and administration site conditions | | Fatigue | | |
| Vascular Disorders | | | | Hypotension |

**Overdose**
The following events have been observed in patients who have taken Monurol in overdose: vestibular loss, impaired hearing, metallic taste, and general decline in taste perception.
In the event of overdosage, treatment should be symptomatic and supportive.
The patient should drink large quantities of water to promote urinary elimination of the drug.

**Shelf-life**
Control the expiry date.

**Special precautions for storage**
Store below 25°C.

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