



substance in adults) is sufficient for recovery. The persistence of local symptoms, if any, after treatment, is not necessarily a sign of therapeutic failure, but usually the consequence of the past inflammation.

- In more clinically problematic cases (elderly, bedridden patients, recurrent infections) or in infections due to microorganisms usually susceptible to the highest antibiotic doses (Pseudomonas, Enterobacter, Indolke - Proteus) two MONUROL doses can be administered at a 24 hr interval.

**Perioperative antibiotic prophylaxis for transrectal prostate biops:**  
1 sachet of Monurol 3g approx. 3 hours before, and 24 hours after the procedure.

**METHOD OF ADMINISTRATION**

For oral use  
For the indication of acute uncomplicated lower urinary tract infections (acute cystitis), Monurol should be taken on an empty stomach (about 2-3 hours before or 2-3 hours after a meal), preferably before bedtime and after emptying the bladder.  
The dose should be dissolved into a glass of water (50 - 75ml) and taken immediately after its preparation.

**SYMPTOMS AND TREATMENT FOR OVERDOSAGE AND ANTIDOTES**

There are limited data on the overdose with oral fosfomycin.

**Signs and symptoms**

Cases of hypotonia, somnolence, electrolyte disturbances, thrombocytopenia, and hypoprothrombinaemia have been reported after parenteral administration of fosfomycin.

**Treatment**

In the event of overdose, the patient must be monitored (particularly for plasma/serum electrolyte levels), and treatment should be symptomatic and supportive. Rehydration is recommended to promote urinary elimination of the active substance. Fosfomycin is effectively cleared from the body by haemodialysis with a mean elimination half-life of approximately 4 hours.

**ADVERSE REACTIONS**

After administration of a single dose of fosfomycin trometamol, the most common adverse effects are those which affect the gastrointestinal tract, primarily diarrhoea. The following frequency criteria are used as the basis for evaluating undesirable effects: 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 from the available data).

**Infections and infestations**

**Common:** Vulvovaginitis.

**Immune system disorders**

**Not known:** Anaphylactic reactions including anaphylactic shock, hypersensitivity (see section «Warnings and precautions»).

**Nervous system disorders**

**Common:** Headache, dizziness.

**Gastrointestinal disorders**

**Common:** Diarrhoea, nausea, dyspepsia, abdominal pain.

**Uncommon:** Vomiting.

**Not known:** Antibiotic-associated colitis (see section «Warnings and precautions»).

**Skin and subcutaneous tissue disorders**

**Uncommon:** Rash, urticaria, pruritus.

**Not known:** Angioedema.

**WARNING AND PRECAUTIONS**

The use of Monurol is not recommended in patients with renal impairment (creatinine clearance < 10 ml/min, see section «Pharmacokinetics»).

Since there is insufficient data for children under 12 years of age, Monurol should not be given to them.

Hypersensitivity reactions, including anaphylaxis and anaphylactic shock, may occur during fosfomycin treatment and may be life-threatening (see section «Adverse Reactions»).

If such reactions occur, fosfomycin should never be re-administered to these patients. An adequate medical treatment is required.

Antibiotic-associated diarrhoea has been reported with the use of nearly all antibacterial agents, including fosfomycin trometamol and may range in severity from mild diarrhoea to fatal colitis. Diarrhoea, particularly if severe and persistent, during or after treatment, may be symptomatic of Clostridium difficile-associated diarrhoea (CDAD). It is therefore important to consider the diagnosis of CDAD in patients who develop serious diarrhoea during or after treatment with Monurol. If CDAD is suspected or confirmed, appropriate treatment should be initiated without delay (see section «Adverse Reactions»). Anti-peristaltic medicinal products are contraindicated in this situation.

In case of persistent infections, a thorough examination and a re-evaluation of the diagnosis is recommended as this is often due to complicated urinary tract infections or the prevalence of resistant pathogens (e.g., Staphylococcus saprophyticus). In general, urinary tract infections in male patients have to be considered as complicated urinary tract infections, for which this medicinal product is not indicated (see section «Indications»).

Monurol contains sucrose. Its use is not recommended in patients with hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency.

**PREGNANCY AND LACTATION**

**Pregnancy**

Only limited data on the safety of fosfomycin trometamol treatment during 1st trimester of pregnancy (n=152) are available. These data do not raise any safety signal for teratogenicity so far. Fosfomycin crosses the placenta. Animal studies have not indicated any direct or indirect toxicity with any effect on pregnancy, embryonic development, development of the foetus and/or postnatal development.

Monurol should only be used during pregnancy, if clearly necessary.

**Lactation**

Since Monurol passes into breast milk even after taking just a single dose, women who are breast-feeding should not be treated with Monurol unless strictly necessary.

**Fertility**

No data in humans are available. In male and female rats, oral administration of fosfomycin up to 1000 mg/kg/d did not impair fertility.

**DRUG INTERACTION**

When co-administered with fosfomycin, metoclopramide significantly lowers the therapeutically effective serum and urine concentrations of fosfomycin. Other drugs that increase the gastrointestinal motility may produce similar effects.

If fosfomycin trometamol is taken with food, the plasma, and urinary levels of fosfomycin decrease. For this reason, it is recommended to take this medicine on an empty stomach or 2 to 3 hours after a meal or after taking other medications.

Specific problems concerning INR (International Normalized Ratio) alteration: numerous cases of increased anti-vitamin K antagonist activity have been reported in patients taking antibiotics. Risk factors include serious infections or inflammations, old age and poor general health. Under these circumstances, it is difficult to determine whether the change in the INR is due to infectious disease or is caused by the treatment. However, there are certain classes of antibiotics which are more frequently involved, in particular: fluoroquinolones, macrolides, cyclines, co-trimoxazole and certain cephalosporins.

Interaction studies have only been carried out in adults.

**EFFECTS ON ABILITY TO DRIVE AND USE MACHINES**

No corresponding studies have been performed. Since Monurol can cause dizziness, this could affect the ability to drive vehicles or use machines.

**PRECLINICAL SAFETY DATA**

Fosfomycin has no mutagenic effect. No toxic effects due to Monurol have been demonstrated in studies on teratogenesis (rats, rabbits), fertility (rats) and pre- and post-natal toxicity (rabbits).

**FORMULATION AND AVAILABILITY**

**GRANULES**  
MONUROL is supplied as granules each sachet containing 3g of Fosfomycin trometamol for the adult dose.

**STORAGE**

Store at room temperature not exceeding 30°C.

**SHELF-LIFE**

3 years

**PACKAGING**

MONUROL single-dose sachet/ box


**KEEP OUT OF THE REACH OF CHILDREN  
DO NOT USE BEYOND EXPIRY DATE**

Manufactured by:  
Zambon Switzerland Ltd.  
Via Industria 13  
6814 Cadempino - Switzerland

**DATE OF REVISION OF PI**

August 2023

H02V602 E05.0922 IS 506 CC-A (CP 8/8)

		Property of Zambon S.p.A Via Lillo del Duca 10 20091 Bresso / Milano		PRODOTTO / BRAND: <b>IS MONUROL BST MY</b>		LATO STAMPA BIANCA/VOLTA (SIDE PRINT FRONT/REAR): <b>LATO VOLTA / BACK SIDE</b>	
CODICE / ITEM: <b>H02V602</b>		ED. / VERSION N.: <b>E05.0922</b>		DATA / DATE: <b>18/08/2023</b>		REV MOCKUP APPROVATO - DATA: <b>NA - 5</b>	
DIMENSIONI / SIZE: <b>135x280 (35)</b>		FORM./TECH.CODE/MASTER LAYOUT: <b>FI506 CC-A</b>		CONFORME AL MASTER LAYOUT - NOTE: <b>FI506 CC-A</b>		FONT/CORPO MIN./INTERLINEA (FONT/MIN. SIZE/SPACING): <b>HELVETICA NEUE</b>	
COD. CLIENTE / CUSTOMER CODE: <b>N/A</b>		PHARMA CODE: <b>138 (IIIXIX)</b>		EDGE CODE: <b>B-E-I</b>		COLORI / COLORS NO: <b>2</b>	
STABILIMENTO / PLANT: <b>CADEMPINO</b>		PACKAGING LINE: <b>N/A</b>		BRILLE: <b>NO</b>		ISTRUZIONI FORNITORE / SUPPLIER INSTRUCTION: <b>N/A</b>	
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