Monural® also known as: Monurol (America), Monuril (Europe)

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Name in Cyrillic: Монурал

Active substance: Fosfomycin tromethamine

Pharmachologic effect: Fosfomycin is an antibiotic indicated in the treatment of non-complicated acute cystitis

(urinary tract infection).

#### **Pharmacokinetics:**

After oral administration, fosfomycin tromethamine is converted to a free acid, which is rapidly absorbed from the gastrointestinal tract. After taking a single oral dose of fosfomycin tromethamine (equivalent to 3 g of fosfomycin),  $C_{max}$  in serum is reached within 2 hours and is 26.1  $\mu$ g / ml when taken on an empty stomach.

#### **Indications:**

Acute uncomplicated infections of the lower urinary tract (acute cystitis) in women aged 18 years and older, caused by fosfomycin-sensitive pathogens Escherichia coli, Enterococcus faecalis. Fosfomycin is not indicated for the treatment of pyelonephritis or perinephric abscess.

**Contraindications:** Hypersensitivity to fosfomycin.

### Pregnancy and breast-feeding:

Fosfomycin crosses the placental barrier and its safety in the treatment of infections during pregnancy has not been established. Fosfomycin should be used during pregnancy only for absolute indications and only after taking into account the ratio of potential benefit to the mother and risk to the fetus.

Fosfomycin may be excreted in breast milk, and a decision should be made whether to stop breastfeeding or not to use fosfomycin, taking into account the potential benefit to the mother and the risk to the newborn.

#### Side effects:

According to the studies, the most common adverse reactions that occurred in > 1% of patients, regardless of the association with the use of drugs, were diarrhea (10.4%), headache (10.3%), vaginitis (7.6%), nausea (5, 2%), rhinitis (4.5%), back pain (3.0%), dysmenorrhea (2.6%), pharyngitis (2.5%), dizziness (2.3%), abdominal pain (2.2%), pain (2.2%), dyspepsia (1.8%), asthenia (1.7%) and rash (1.4%).

# Interaction:

Metoclopramide. With the simultaneous use of fosfomycin and metoclopramide, which increases gastrointestinal motility, the concentration of fosfomycin in the blood serum and its excretion in the urine decrease. Other drugs that increase gastrointestinal motility may have a similar effect.

Probenecid. Probenecid should not be co-administered with fosfomycin as it has been shown to significantly reduce the renal clearance and excretion of fosfomycin.

Probenecid, when administered to healthy volunteers receiving an infusion of disodium fosfomycin, significantly reduced renal clearance, probably due to inhibition of tubular secretion, which led to a decrease in the concentration of the drug in the urine.

Cimetidine. Cimetidine does not affect the pharmacokinetics or urinary concentrations of fosfomycin when co-administered.

Eating. Food intake delays the absorption of fosfomycin, which leads to a decrease in Cmax in blood plasma and

concentration in urine. Therefore, it is recommended that fosfomycin tromethamine be taken on an empty stomach or at least 2 to 3 hours after a meal.

# **Dosing and Administration:**

### Dosing:

For the treatment of acute cystitis the recommended dose is 1 sachet of Monural (3 g Fosfomycin).

When used as antibiotic prophylaxis for transrectal prostate biopsy the recommended dose is 1 sachet of Monural (3 g fosfomycin) 3 hours prior to the procedure and 1 sachet of Monural 24 hours after the procedure.

# Administration:

- 1. Empty entire contents of Monural sachet into 100 ml ( 3-4 ounces) of water, and stir to dissolve. Do not use hot water
- 2. Take immediately after dissolving in water, making sure to drink complete contents of glass.

#### **Special instructions:**

The pain usually subsides within the first few hours after administration of Monural, but in some cases, due to the infection, the pain may persist for 24 to 48 hours. This time lag should not worry you. However, if after this time period the pain persists, contact your doctor.

Monural® contains 2.213g of sucrose per sachet. It should not be used by patients with fructose intolerance, glucose and galactose malabsorption syndrome or sucrase-isomaltase deficiency (rare metabolic diseases).

Manufacturer: Zambon (Switzerland)

# Reliable supplier with fast Worldwide shipping:

RussianMeds Online Store <a href="https://russianmeds.com">https://russianmeds.com</a>

# Storage:

The temperature is not above 30 °C (86 °F)