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Monurol

(Fosfomycin Tromethamine) - Forest

THERAPEUTIC CLASS

Phosphonic acid derivative

DEA CLASS

RX

INDICATIONS

Treatment of uncomplicated urinary tract infections (acute cystitis) in women due to susceptible strains of microorganisms.

ADULT DOSAGE

Adults: ≥18 yrs: 1 single-dose sachet.

HOW SUPPLIED

Powder: 3g/sachet

WARNINGS/PRECAUTIONS

Avoid use of >1 single dose per episode of acute cystitis. *Clostridium difficile*-associated diarrhea (CDAD) reported. Other therapeutic agents may be selected if persistence or reappearance of bacteriuria occurs after treatment. Caution in elderly.

ADVERSE REACTIONS

Diarrhea, headache, vaginitis, nausea, rhinitis, back pain.

DRUG INTERACTIONS

Metoclopramide and other drugs that increase GI motility may decrease serum concentrations and urinary excretion.

PREGNANCY

Category B, not for use in nursing.

MECHANISM OF ACTION

Phosphonic acid derivative; inactivates enolpyruvyl transferase, irreversibly blocking condensation of uridine diphosphate-N-acetylglucosamine with p-enolpyruvate, one of the first steps in bacterial cell wall synthesis. Also reduces adherence of bacteria to uroepithelial cells.

PHARMACOKINETICS

Absorption: Rapid; absolute bioavailability (37%) (fasted); C_{max} =26.1 µg/mL, 17.6 µg/mL (fed); T_{max} =2 hrs, 4 hrs (fed). **Distribution:** V_d =136.1L; crosses placental barrier. **Elimination:** Urine (38% unchanged), feces (18% unchanged); $T_{1/2}$ =5.7 hrs.

ASSESSMENT

Assess for hypersensitivity, pregnancy/nursing status, and for possible drug interactions. Obtain urine specimens for culture and susceptibility testing prior to therapy.

MONITORING

Monitor for CDAD and other adverse reactions. Monitor for persistence or reappearance of bacteriuria after therapy. Obtain urine specimens for culture and susceptibility testing after completion of therapy.

PATIENT COUNSELING

Instruct to take with or without food. Advise to seek medical attention if symptoms do not improve within 2-3 days. Inform that diarrhea is a common problem that usually ends when antibiotic is d/c. Advise that watery and bloody stools (with or without stomach cramps and fever) may develop even as late as ≥2 months after last dose; notify physician immediately if this occurs.

ADMINISTRATION/STORAGE

Administration: Oral route. Do not take in dry form. Pour contents of single-dose sachet into 3-4 oz. of water (1/2 cup); stir to dissolve (do not use hot water). Take immediately after dissolving. **Storage:** 25°C (77°F); excursions permitted to 15-30°C (59-86°F).

