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Tygacil

(Tigecycline) - Wyeth

BOXED WARNING

An increase in all-cause mortality observed in clinical trials; should be reserved for use in situations when alternative treatment are not suitable.

THERAPEUTIC CLASS

Glycylcycline

DEA CLASS

RX

INDICATIONS

Treatment of complicated skin and skin structure infections (cSSSIs), complicated intra-abdominal infections (cIAIs), and community-acquired bacterial pneumonia (CABP) caused by susceptible strains of indicated pathogens in patients ≥18 yrs of age.

ADULT DOSAGE

Adults: ≥18 Yrs: Give IV over 30-60 min. Initial: 100mg. Maint: 50mg q12h for 5-14 days (cSSSIs/cIAIs) or for 7-14 days (CABP). Duration of therapy should be guided by severity of infection. Severe Hepatic Impairment (Child-Pugh C): Initial: 100mg. Maint: 25mg q12h.

PEDIATRIC DOSAGE

Pediatrics: Should not be used unless no alternative antibacterial drugs are available. Give IV over 30-60 min. 12-17 Yrs: 50mg q12h. 8-11 Yrs: 1.2mg/kg q12h. Max: 50mg q12h.

HOW SUPPLIED

Inj: 50mg [5mL, 10mL]

WARNINGS/PRECAUTIONS

Not indicated for the treatment of diabetic foot infections and hospital-acquired or ventilator-associated pneumonia. Anaphylaxis/anaphylactoid reactions reported. Caution with known hypersensitivity to tetracycline-class antibiotics. Isolated cases of significant hepatic dysfunction and hepatic failure reported; adverse events may occur after therapy has been discontinued. Acute pancreatitis reported; consider stopping therapy if suspected. May cause fetal harm in pregnant women and permanent tooth discoloration (yellow-gray-brown) when administered during tooth development (last 1/2 of pregnancy to 8 yrs of age). *Clostridium difficile*-associated diarrhea (CDAD) reported; d/c if CDAD is suspected or confirmed. Caution when used for cIAI secondary to clinically apparent intestinal perforation. Structurally similar to tetracyclines; may have similar adverse effects (eg, photosensitivity, pseudotumor cerebri, antianabolic action [may lead to increased BUN, azotemia, acidosis, hyperphosphatemia]). May result in overgrowth of nonsusceptible organisms; take appropriate measures if superinfection develops. Use in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit and increases the risk of development of drug-resistant bacteria. Caution in patients with severe hepatic impairment (Child-Pugh C) and monitor for treatment response.

ADVERSE REACTIONS

Abdominal pain, asthenia, headache, infection, N/V, phlebitis, diarrhea, anemia, dizziness, rash, abnormal healing, increased alkaline phosphatase/BUN/liver enzymes (SGOT/SGPT), hypoproteinemia.

DRUG INTERACTIONS

May render oral contraceptives less effective. Monitor PT or other suitable anticoagulation test with warfarin.

PREGNANCY

Category D, caution in nursing.

MECHANISM OF ACTION

Glycylcycline; inhibits protein translation in bacteria by binding to the 30S ribosomal subunit and blocking entry of amino-acyl tRNA molecules into the A site of the ribosome.

PHARMACOKINETICS

Absorption: Single Dose: (100mg) C_{max}=1.45mcg/mL (30 min infusion), 0.90mcg/mL (60 min infusion); AUC=5.19mcg•hr/mL. Multiple Dose: (50mg q12h) C_{max}=0.87mcg/mL (30 min infusion), 0.63mcg/mL (60 min infusion); $AUC_{0-24\ hr}$=4.7mcg•hr/mL. **Distribution:** V_d=7-9L/kg; plasma protein binding (71-89%). **Elimination:** Bile (59%), urine (33%, 22% unchanged); $T_{1/2}$=27.1 hrs (single dose), 42.4 hrs (multiple dose).

ASSESSMENT

Assess for known hypersensitivity to tetracycline-class antibiotics, hepatic impairment, cIAI secondary to clinically apparent intestinal perforation, culture and susceptibility testing, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for signs/symptoms of hypersensitivity reactions, hepatic impairment, pancreatitis, photosensitivity, superinfection, CDAD and other adverse reactions.

PATIENT COUNSELING

Inform that therapy only treats bacterial, not viral, infections. Instruct to take exactly ud even if the patient feels better early in the course of therapy; skipping doses or not completing the full course of therapy may decrease effectiveness and increase risk of bacterial resistance. Advise that diarrhea is a common problem that usually ends when therapy is discontinued; however, if watery and bloody stools (with/without stomach cramps and fever) occur, even as late as 2 or more months after last dose, instruct to contact physician as soon as possible. Advise of risk of fetal harm during pregnancy.

ADMINISTRATION/STORAGE

Administration: IV route. Refer to PI for preparation and handling details. **Storage:** Prior to Reconstitution: (Powder) 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F). Reconstituted Sol: Room temperature (not to exceed 25°C [77°F]) up to 24 hrs (up to 6 hrs in vial and remaining time in IV bag); use immediately if storage conditions exceed 25°C (77°F). Mixed with 0.9% NaCl Inj or D5 Inj: 2-8°C (36-46°F) for up to 48 hrs following immediate transfer of reconstituted solution into IV bag.