CLAVIFORD 625

To reduce the development of drug-resistant bacteria and maintain the effectiveness of CLAVIFORD 625 and other antibacterial drugs, CLAVIFORD 625 should be used only to treat infections that are proven or strongly suspected to be caused by bacteria.

----------INDICATIONS AND USAGE ----------

CLAVIFORD 625 is a combination penicillin-class antibacterial and beta-lactamase inhibitor indicated for treatment of the following:

Lower respiratory tract infections (1.1)

Acute bacterial otitis media (1.2)

Sinusitis (1.3)

Skin and skin structure infections (1.4)

Urinary tract infections (1.5)

----------DOSAGE AND ADMINISTRATION----------

• Adults and Pediatric Patients > 40 kg: 500 or 875 mg every 12 hours or 250 or 500 mg every 8 hours. (2.1, 2.2)

• Pediatric patients aged 12 weeks (3 months) and older: 25 to 45 mg/kg/day every 12 hours or 20 to 40 mg/kg/day every 8 hours, up to the adult dose. (2.2)

----------DOSAGE FORMS AND STRENGTHS ----------

Formulations and amoxicillin/clavulanate content are:

500 mg/125 mg, 875

---------- CONTRAINDICATIONS ----------

• History of a serious hypersensitivity reaction (e.g., anaphylaxis or Stevens-Johnson syndrome) to CLAVIFORD 625 or to other beta-lactams (e.g., penicillins or cephalosporins) (4)

• History of cholestatic jaundice/hepatic dysfunction associated with CLAVIFORD 625. (4)

---------- WARNINGS AND PRECAUTIONS ----------

• Serious (including fatal) hypersensitivity reactions: Discontinue CLAVIFORD 625 if a reaction occurs. (5.1) • Hepatic dysfunction and cholestatic jaundice: Discontinue if signs/symptoms of hepatitis occur. Monitor liver function tests in patients with hepatic impairment. (5.2)

• Clostridium difficile-associated diarrhea (CDAD): Evaluate patients if diarrhea occurs. (5.3)

• Patients with mononucleosis who receive CLAVIFORD 625 develop skin rash. Avoid CLAVIFORD 625 use in these patients. (5.4)

• Overgrowth: The possibility of superinfections with fungal or bacterial pathogens should be considered during therapy. (5.5)

---------- **ADVERSE REACTIONS** ----------

The most frequently reported adverse effects were diarrhea/loose stools (9%), nausea (3%), skin rashes and urticaria (3%), vomiting (1%) and vaginitis (1%) (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact GlaxoSmithKline at 1-888-825-5249 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

---------- **DRUG INTERACTIONS**----------

• Co-administration with probenecid is not recommended. (7.1)

• Concomitant use of CLAVIFORD 625 and oral anticoagulants may increase the prolongation of prothrombin time. (7.2)

• Coadministration with allopurinol increases the risk of rash. (7.3)

• CLAVIFORD 625 may reduce efficacy of oral contraceptives. (7.4)

---------- **USE IN SPECIFIC POPULATIONS** ----------

• Pediatric Use: Modify dose in patients 12 weeks or younger. (8.4)

• Renal impairment; Dosage adjustment is recommended for severe renal impairment (GFR< 30mL/min). (2.3, 8.6)