ALTIPOD CV 100

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory only

Abbreviated Prescribing information for Altipod CV 100 (Cefpodoxime Proxetil 100 mg and Potassium Clavulanate 62.5 mg Dispersible Tablets) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Cefpodoxime proxetil is an extended spectrum, semi-synthetic antibiotic of the cephalosporin class and clavulanate potassium is the β-lactamase inhibitor.

INDICATION: It is indicated for the treatment of infection caused by susceptible microorganisms in lower and upper respiratory infections and urinary tract infection.

DOSAGE AND ADMINISTRATION: It should be taken with food to enhance absorption. The tablets should be swallowed whole and not chewed, broken, or crushed. *Total Daily Dose of cefpodoxime Adults and Adolescents (age 12 years and older):* 200-400mg depends on type of infection and *for Infants and Pediatric Patients (age 2 months through 12 years):* 10 mg/kg/day (Max 400 mg/day).

CONTRAINDICATION: It is contraindicated in patients with a known allergy to penicillin, any other type of beta-lactam drug, cephalosporin class of antibiotics, beta-lactamase inhibitors or any other ingredients of this formulation.

WARNINGS & PRECAUTIONS: Careful inquiry should be made before starting whether the patient has had previous hypersensitivity reactions to cefpodoxime, other cephalosporins, penicillins, or other drugs. Caution should be exercised for Clostridium difficile associated diarrhea. In patients with renal insufficiency, the total daily dose of cefpodoxime proxetil should be reduced. Like other cephalosporins, it should be administered with caution to patients receiving concurrent treatment with potent diuretics. Prolonged use of cefpodoxime proxetil may result in overgrowth of nonsusceptible organisms. In patients with treatment lasting for longer than 10 days, blood count should therefore be monitored, and discontinue the treatment if neutropenia is found. It can produce a positive Coombs' test and very rarely, haemolytic anemia. Changes in renal function have been observed with antibiotics of the same class, particularly when given concurrently with potentially nephrotoxic drugs hence renal function should be monitored.

DRUG INTERACTIONS: Concomitantly given antacid or H_2 blockers may reduce peak plasma levels and the extent of absorption. Oral anti-cholinergics delays its peak plasma levels. Renal excretion of cefpodoxime was inhibited by probenecid and resulted in increased peak plasma levels. Close monitoring of renal function is advised when cefpodoxime proxetil is given concomitantly with other nephrotoxic drugs. The bioavailability increases if the product administered during meals. A false positive reaction for glucose may occur with Benedict's or Fehling's solutions or with copper sulphate test tablets but not with tests based on enzymatic glucose oxidase reactions.

ADVERSE REACTIONS: Diarrhea/Clostridium difficile associated diarrhea (CDAD), gastrointestinal disturbances, nausea, vomiting, vaginal fungal infections, vulvovaginal infections, malaise, fatigue, asthenia, fever, chest pain, congestive heart failure, flatulence, anemia, dehydration, gout, peripheral edema, weight increase, myalgia, dizziness, insomnia, somnolence, anxiety, nervousness, asthma, cough, urticaria, rash, taste alterations, eye irritation, hematuria, syncope,

Vaginitis, transient increases in AST, ALT, GGT, ALP and ADH, hematologic and serum chemistry may affected.

MARKETED BY:

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(Additional information is available on request)