DROXYL CLAV 250

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

Abbreviated Prescribing information for DROXYL CLAV 250 (Cefadroxil And Potassium Clavulanate Dispersible Tablets**)**

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Cefadroxil is a cephalosporin for oral administration which inhibits bacterial wall synthesis of actively dividing cells by binding to one or more penicillin-binding proteins. The result is formation of a defective cell wall that is osmotically unstable, and bacterial cell lysis. Clavulanic acid is a beta-lactam structurally related to penicillins. It inactivates some beta-lactamase enzymes thereby preventing inactivation of amoxicillin. Clavulanic acid alone does not exert a clinically useful antibacterial effect.

DOSAGE AND ADMINISTRATION: One tablet once daily or as directed by Physician. *Method of administration*: Disperse Cefadroxil and Potassium Clavulanate Dispersible Tablets in a glass of water before administration.

CONTRAINDICATION: Patients with known hypersensitivity to cephalosporin antibiotics.

WARNINGS & PRECAUTIONS: Serious and occasionally fatal hypersensitivity (anaphylactic) reactions in patients on penicillin therapy. *Clostridium difficile* associated diarrhea (CDAD), with use of nearly all antibacterial agents, including Cefadroxil, and may range in severity from mild diarrhea to fatal colitis. Cefadroxil should be used with caution in the presence of markedly impaired renal function (creatinine clearance rate of less than 50 mL/min/1.73 m^2). In patients with known or suspected renal impairment, careful clinical observation and appropriate laboratory studies should be made prior to and during therapy. *Drug/Laboratory Test Interactions:* Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

DRUG INTERACTION: *Contraindication of concomitant use:* Cefadroxil should not be combined with bacteriostatic antibiotics (e.g. tetracycline, erythromycin, sulfonamides, chloramphenicol) since an antagonistic effect is possible and with aminoglycoside antibiotics, polymyxin B, colistin or high-dose loop diuretics should be avoided since such combinations can potentiate nephrotoxic effects. *Concomitant use not recommended:* Frequent checks on coagulation parameters are necessary during concomitant long term use of anticoagulants or thrombocyte aggregation inhibitors to avoid haemorrhagic complications. *Precautions:* The concomitant administration of probenicid can produce higher and sustained concentrations of cefadroxil in the serum and in the bile. The occurence of diarrhoea may impair the resorption of other medicaments and therefore lead to an impairment of their efficacy. Forced diuresis leads to a decrease of cefadroxil blood levels. Cefadroxil attenuate the effect of oral contraceptives. Cefadroxil binds to cholestyramine, which may lead to reduced bioavailability of cefadroxil.

ADVERSE REACTIONS: *Gastrointestinal:* Onset of pseudomembranous colitis symptoms occur during or after antibiotic treatment. Dyspepsia, diarrhea, nausea, vomiting, indigestion, gastritis, stomatitis, glossitis, black “hairy” tongue, mucocutaneous candidiasis, enterocolitis, and hemorrhagic/pseudomembranous colitis have been reported. *Hypersensitivity:* Allergies

(in the form of rash, urticaria, angioedema, and pruritus), anaphylaxis, Skin rashes, pruritus, urticaria, angioedema, serum sickness - like reactions (urticaria or skin rash accompanied by arthritis, arthralgia, myalgia, and frequently fever), erythema multiforme (rarely Stevens-Johnson syndrome), acute generalized exanthematous pustulosis, hypersensitivity vasculitis, and an occasional case of exfoliative dermatitis (including toxic epidermal necrolysis) have been reported. *Other:* Hepatic dysfunction including cholestasis and elevations in serum transaminase, genital pruritus, genital moniliasis, vaginitis, moderate transient neutropenia, fever, agranulocytosis, thrombocytopenia, idiosyncratic hepatic failure, erythema multiforme, Stevens - Johnson syndrome, serum sickness, and arthralgia have been rarely reported. *Altered laboratory tests*: for cephalosporin-class antibiotics: Toxic epidermal necrolysis, abdominal pain, superinfection, renal dysfunction, toxic nephropathy, aplastic anemia, haemolytic anemia, hemorrhage, prolonged prothrombin time, positive Coombs' test, increased BUN, increased creatinine, elevated alkaline phosphatase, elevated aspartate aminotransferase (AST), elevated alanine aminotransferase (ALT), elevated bilirubin, elevated LDH, eosinophilia, pancytopenia, neutropenia. Allergic exanthema, angioneurotic edema, leucopenia, haemolytic anaemia of immunologic origin, headache, nervousness, sleeplessness, fatigue, opportunistic infections (e.g. vaginal mycoses, thrush). *Renal:* Interstitial nephritis and hematuria, Crystalluria. Cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment, when the dosage was not reduced.

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(Additional information is available on request)