U.V.A. CEF-CV 50 DRY SYRUP

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

Abbreviated Prescribing information for U.V.A. CEF-CV DRY SYRUP (Cefpodoxime Proxetil 50 mg and Potassium Clavulanate 31.25 mg Oral Suspension**)**

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

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: The mechanism of action of cefpodoxime is based on inhibition of bacterial cell wall synthesis. Cefpodoxime has been shown to possess in vitro bactericidal activity against numerous gram-positive and gram-negative bacteria. Cefpodoxime is stable in the presence of β-lactamase enzymes. In particular, Clavulanic acid has good activity against the clinically important plasmid-mediated β-lactamases frequently responsible for transferred drug resistance. It blocks the destructive hydrolytic activity of β-lactamases sparing cefpodoxime from hydrolysis. The presence of clavulanic acid in the cefpodoxime + clavulanic acid tablets effectively extends the antibiotic spectrum of cefpodoxime to include many bacteria normally resistant to it and to other β-lactam antibiotics. Thus, cefpodoxime + clavulanic acid tablets (FDC Cefpodoxime + Clavulanic Acid) possess the properties of a broad- spectrum antibiotic and a β-lactamase inhibitor.

DOSAGE AND ADMINISTRATION: As directed by physician.

CONTRAINDICATION: Cefpodoxime + Clavulanic Acid Tablets (FDC Cefpodoxime + Clavulanic Acid) are 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: before therapy with cefpodoxime proxetil is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cefpodoxime, other cephalosporins, penicillins, or other drugs. If cefpodoxime is to be administered to penicillin sensitive patients, caution should be exercised because cross hypersensitivity among β-lactam antibiotics has been clearly Documented and may occur in up to 10% of patients with a history of penicillin allergy. If an allergic reaction to cefpodoxime proxetil occurs, discontinue the drug. Serious acute hypersensitivity reactions may require treatment with epinephrine and other emergency measures, including oxygen, intravenous fluids, intravenous antihistamine, and airway management, as clinically indicated.

DRUG INTERACTION: Antacids: Concomitant administration of high doses of antacids (sodium bicarbonate and aluminum hydroxide) or H2 blockers reduces peak plasma levels by 24% to 42% and the extent of absorption by 27% to 32%, respectively. The rate of absorption is not altered by these concomitant medications. Oral anti-cholinergics (e.g., propantheline) delay peak plasma levels (47% increase in Tmax), but do not affect the extent of absorption (AUC), Probenecid, Nephrotoxic drugs, Food: The bioavailability increases if the product is administered during meals. Drug/Laboratory Test Interactions: A false positive reaction for glucose in the urine 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, nausea, vaginal fungal infections, vulvovaginal infections, abdominal pain, headache, fungal infections, abdominal distention, malaise, fatigue, asthenia, fever, chest pain, back pain, chills, generalized pain, abnormal microbiological tests, moniliasis, abscess, allergic reaction, facial edema, bacterial infections, parasitic infections,

localized edema, localized pain, congestive heart failure, migraine, palpitations, vasodilation, hematoma, hypertension, hypotension, vomiting, dyspepsia, dry mouth, flatulence, decreased appetite, constipation, oral moniliasis, anorexia, eructation, gastritis, mouth ulcers, gastrointestinal disorders, rectal disorders, tongue disorders, tooth disorders, increased thirst, oral lesions, tenesmus, dry throat, toothache, myalgia, dizziness, insomnia, somnolence, anxiety, shakiness, nervousness, cerebral infarction, change in dreams, impaired concentration, confusion, nightmares, paresthesia, vertigo, asthma, cough, epistaxis, rhinitis, wheezing, bronchitis, dyspnea, pleural effusion, pneumonia, sinusitis, urticaria, rash, pruritus non-application site, diaphoresis, maculopapular rash, fungal dermatitis, desquamation, dry skin non-application site, hair loss, vesiculobullous rash, sunburn, hematuria, urinary tract infections, metrorrhagia, dysuria, urinary frequency, nocturia, penile infection, proteinuria, vaginal pain, Transient increases in AST (SGOT), ALT (SGPT), GGT, alkaline phosphatase, bilirubin, and LDH, Eosinophilia, leukocytosis, lymphocytosis, granulocytosis, basophilia, monocytosis, thrombocytosis, decreased hemoglobin, decreased hematocrit, leukopenia, neutropenia, lymphocytopenia, thrombocytopenia, thrombocythemia, positive Coombs' test, and prolonged PT, and PTT, Hyperglycemia, hypoglycemia, hypoalbuminemia, hypoproteinemia, hyperkalemia, and hyponatremia, Increases in BUN and creatinine.

Manufactured by:
Hetero Labs Limited (Unit - I)
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(Additional information is available on request)