

SEFDIN

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

Abbreviated Prescribing information for SEFDIN [Cefdinir Capsules I.P. 300 mg]

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

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION As with other cephalosporins, bactericidal activity of Cefdinir results from inhibition of cell wall synthesis by acting on penicillin binding proteins (PBPs).

INDICATIONS: It is indicated for treatment of community acquired pneumonia, acute exacerbation of chronic bronchitis, uncomplicated skin & skin structure infection, pharyngitis/tonsillitis, acute maxillary sinusitis & acute bacterial otitis media additional.

DOSAGE AND ADMINISTRATION: The recommended dosage and duration of treatment for infections in adults and Adolescents are described in the following chart: the total daily dose for all infections is 600 mg. Once-daily dosing for 10 days is as effective as BID dosing. Once-daily dosing Has not been studied in pneumonia or skin infections; therefore, Cefdinir Capsules Should be administered twice daily in these infections. Cefdinir Capsules may be taken without regard to meals.

CONTRAINDICATION: Cefdinir is contraindicated in patients with known allergy to the cephalosporin class of antibiotics.

WARNINGS & PRECAUTIONS: Before therapy with Cefdinir is instituted, Careful inquiry should be made to determine whether the Patient has had previous hypersensitivity reactions to Cefdinir, other cephalosporins, penicillins, or other drugs. If Cefdinir is to be given to penicillin-sensitive patients, Caution should be exercised because cross-hypersensitivity.

DRUG INTERACTIONS: Concomitant administration of 300-mg Cefdinir capsules with 30 mL Maalox® TC suspension reduces the rate (C_{max}) and extent (AUC) of absorption by approximately 40%. Time to reach C_{max} is also prolonged by 1 hour. There are no significant effects on Cefdinir pharmacokinetics if the antacid is administered 2 hours before or 2 hours after Cefdinir. If antacids are required during CEFDINIR therapy, CEFDINIR should be taken at least 2 hours before or after the antacid.

ADVERSE REACTIONS: Vaginal moniliasis, Nausea, Headache, Abdominal pain, Vaginitis, Rash, Dyspepsia, Flatulence, Vomiting, Abnormal stools, Anorexia, Constipation, Dizziness, Dry mouth, Asthenia, Insomnia, Leucorrhoea, Moniliasis, Pruritus, Somnolence, Diarrhea, Increased Urine leukocytes, Increased Urine protein, Increased Gamma-glutamyl transferase, Decreased Lymphocytes, Increased Microhematuria,

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MARKETED BY:

TORRENT PHARMACEUTICALS LTD.

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(Additional information is available on request)