Cefida®

Cefdinir
Capsule/Suspension

Cefida® (Cefdinir) is a third generation semisynthetic Cephalosporin antibiotic. It has a broad-spectrum bactericidal activity against a wide range of common pathogens, including β-lactamase producing strains. Cefdinir has good stability to bacterial β-lactamase and consequently, is active against many Ampicillin-resistant and Amoxicillin-resistant strains.

Indication and Uses

Cefida® (Cefdinir) is indicated for the treatment of –

- Community Acquired Pneumonia
- Acute Exacerbation of Chronic Bronchitis
- Acute Maxillary Sinusitis
- Pharyngitis/Tonsillitis
- Uncomplicated Skin and Skin Structure Infections

Dosage Uses 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. Cefida® may be taken without regard to meals.

Adults and Adolescents (Age 13years and older)

Types of Infections	Dosage	Duration
Community Acquired Pneumonia	300 mg q:12h	10 days
Acute Exacerbation of Chronic Bronchitis	300 mg q: 12h or 600mg q: 24h	5 to 10 days
Acute Maxillary Sinusitis	300 mg q: 12h or 600mg q: 24h	10 days 10 days
Pharyngitis/Tonsillitis	300mg q: 12h or 600mg q: 24h	5 to 10 days 10 days
Uncomplicated Skin and Skin Structure Infections	300mg q: 12h	10 days

Pediatric Patients (Age 6 months through 12 years)

Types of Infections	Dosage	Duration
Acute Bacterial Otitis Media	7 mg/kg q: 12h or 14 mg/kg q: 24h	5 to 10 days 10 days
Acute Maxillary Sinusitis	7 mg/kg q: 12h or 14 mg/kg q: 24h	10 days 10 days
Pharyngitis/Tonsillitis	7 mg/kg q: 12h or 14 mg/kg q: 24h	5 to 10 days 10 days
Uncomplicated Skin and Skin Structure Infections	7 mg/kg q: 12h	10 days

Contraindication

Cefdinir is contraindicated in patients with known allergy to the cephalosporins class of antibiotics.

Side Effects

In clinical trials, 5093 adult and adolescent patients (3841 US and 1252 non-US) were treated with the recommended dose of Cefdinir capsules (600 mg/day). Most adverse events were mild and self-limiting. No death or permanent disabilities were attributed to Cefdinir. One hundred forty seven of 5093 (3%) patients discontinued medication due to adverse event thought by the investigations to be possibly, probably, or definitely associated with Cefdinir therapy. The discontinuations were primarily for gastrointestinal disturbances, usually diarrhea or nausea, Nineteen of 5093 (0.4%) patients were discontinued due to rash thought related to Cefdinir administration.

Acute overdosage: Excessively large doses of all cephalosporins can cause cerebral irritation and may cause convulsions. This complication is unlikely to occur in routine practice unless the patient is in renal failure. Hemodialysis or peritoneal dialysis can remove Cefdinir.

Precautions

As with other broad spectrum antibiotics, prolonged treatment may result in the possible emergence and overgrowth of resistant organisms. Careful observation of the patient is essential. If superinfection occurs during therapy appropriate alternative therapy should be administered.

Cefdinir as with other broad spectrum anti-microbials (antibiotics), should be prescribed with caution in individuals with a history of colitis.

In patients with transient or persistent renal insufficiency (creatinine clearance <30 mL/min), the total daily dose of Cefdinir should be reduced.

Use in Pregnancy & Lactation

Cefdinir is not teratogenic in rats at oral doses up to 1000 mg/kg/day (70 times the human dose based on mg/kg/day, 11 times based on mg/ml/day) or in rabbits at oral doses up to 10 mg/kg/day (0.7 times the human dose based on mg/kg/day, 0.23 times based on mg/ml/day).

There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Following administration of single 600-mg doses, Cefdinir was not detected in human breast milk.

Lactation category: L2 (Safer): This drug has been studied in a limited number of breast feeding women without an increase in adverse effects in the infant. And the evidence of a demonstrated risk which is likely to follow the use of this medication in a breastfeeding woman is remote. However this drug should be used with caution in nursing women.

Pharmaceutical Precaution

Store in a cool and dry place, protect from light and moisture.

Direction for reconstitution of suspension

Reconstitute the powder with 40 ml of boiled and cooled water to make 60 ml suspension with vigorous shaking. Use the suspension within 7 days after reconstitution. Shake well before each use.

Commercial Pack

Cefida® capsule : Box containing 1 x 10's capsule in blister strip. Each capsule contains Cefdinir INN 300 mg.

Cefida® Powder for Suspension : Bottle containing dry powder for preparation of 60 ml suspension. After reconstitution, each 5 ml contains Cefdinir INN 125 mg.

BEXIMCO PHARMA

Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

TONGI, BANGLADESH BL4111 080905