OMNICEF®

(Cefdinir)

ACTION

Omnicef, developed by Astellas Research Laboratories, is a broad spectrum semisynthetic cephalosporin antibiotic for oral administration. The bactericidal mode of action of Omnicef is a result of the inhibition of cell wall synthesis. Omnicef is highly beta-lactamase stable and as a result, many organisms resistant to penicillins and some cephalosporins, due to the presence of beta-lactamases, are susceptible to Omnicef.

INDICATIONS

Most strains of the following Gram-positive and Gram negative organisms have been shown to be susceptible to Omnicef: *Staphylococcus species, Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus agalactiae, and Streptococcus viridans; Haemophilus influenzae, Haemophilus parainfluenzae, Moraxella catarrhalis, Neisseria gonorrhea and meningitidis, Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, and Citrobacter diversus.*

Therefore Omnicef is indicated in the treatment of:

- Pharyngitis, tonsillitis, pneumonia, bacterial bronchitis, acute exacerbations of chronic bronchitis, acute otitis media, acute maxillary sinusitis, uncomplicated skin and skin structure infections and urinary tract infections.

DOSAGE AND ADMINISTRATION

Adults:

The recommended daily dose of Omnicef is 600 mg. This may be given as a 300 mg capsule once every 12 hours or as two 300 mg capsules once daily.

Omnicef should be administered twice daily in pneumonia or skin infections.

Children:

The recommended dose is 7 mg/kg of suspension every 12 hours or 14 mg/kg once daily up to a maximum of 600 mg per day. Omnicef suspension should be administered twice daily in skin infections in children.

Weight (kg)	**Dose of (125 mg/5 ml suspension)***
9	2.5 ml (0.5 tsp) q 12 hr or 5 ml (1 tsp) q 24 h
18	5 ml (1tsp) q 12 hr or 10 ml (2 tsp) q 24h
27	7.5 ml (1.5 tsp) q 12 hr or 15 ml (3 tsp) q 24 hr

* After reconstitution

Children weighing more than 43 kg should receive the maximum daily dose of 600 mg.

Renal impairment: Cefdinir is renally excreted.

Adults: When creatinine clearance < 30 ml/min, the dose of Omnicef should be 300 mg given once daily.

Children: Pediatric patients with a creatinine clearance of < 30 ml/min/1.73 m^2 should receive Omnicef 7 mg/kg (up to 300 mg) given once daily.

In patients on hemodialysis the recommended dosage is 300 mg or 7 mg/kg every other day.

CONTRAINDICATIONS

Cefdinir is contraindicated in patients with known allergy to the cephalosporin or penicillin group of antibiotics.

WARNINGS

Before therapy with Omnicef is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity to Cefdinir, other cephalosporins or penicillins.

PRECAUTIONS

Cefdinir, as with other broad-spectrum antibiotics, should be prescribed with caution in patients with a history of colitis. No adequate and well-controlled studies have been performed in pregnant women; therefore, this drug should be used during pregnancy only if clearly needed (rated FDA pregnancy category B).

Cefdinir was not detected in human breast milk after administration of 600 mg doses.

In renal insufficiency the total daily dose of Cefdinir should be reduced.

Drug Interactions

Antacids and Iron supplements - Omnicef should be taken at least 2 hours before or after the antacid or Iron supplement.

Reddish stool in patients receiving Cefdinir, and in many cases patients who are also receiving iron containing products, the reddish color is due to the formation of a non absorbable complex between Cefdinir or its breakdown products and iron in the gastrointestinal tract.

Probenecid - Probenecid inhibits the renal excretion of Cefdinir resulting in higher serum concentrations and a longer half-life.

SIDE EFFECTS

Side effects are mild and transient in nature; most of them being diarrhea, abdominal pain, nausea, vomiting, skin rash, transient elevation in liver enzymes.

OVERDOSAGE

Cefdinir is removed from the body by haemodialysis. No information regarding Cefdinir overdosage is available but overdosage with other ß-lactam antibiotics has resulted in nausea, vomiting, epigastric distress, diarrhea and convulsions.

STORAGE

Capsules: Do not store above 30° .

Suspension: Do not store dry powder and reconstituted suspension above 30°C.

PRESENTATIONS

Capsules

OMNICEF 300: Cefdinir 300 mg/capsule

Excipients: Carmellose calcium, magnesium stearate, polyoxyl 40 stearate.

Suspension

OMNICEF 125: Cefdinir 125 mg/5 ml*

Excipients: Citric acid anhydrous, sodium benzoate, trisodium citrate anhydrous, guargum, xanthan gum, strawberry powder flavor, magnesium stearate, colloidal silicon dioxide, sugar.

* After reconstitution

THIS IS A MEDICAMENT

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous.
- Follow the doctor's prescription strictly, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

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Manufactured by Jazeera Pharmaceutical Industries, Riyadh - Saudi Arabia,
for HIKMA Pharmaceuticals, Amman - Jordan

Keep medicament out of the reach of children

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