Otid®

Suspension / Capsules

(Cephradine)

DESCRIPTION:

Otid® (Cephradine) is a semisynthetic cephalosporin antibiotic; oral dosage forms include capsules containing 250mg and 500mg cephradine and cephradine for oral suspension containing, after reconstitution, 125mg and 250mg / 5ml dose

COMPOSITION:

Otid® 125mg/5ml Suspension
Each 5ml of reconstituted suspension contains:
Cephradine USP……..125mg

Otid® 250mg/5ml Suspension
Each 5ml of reconstituted suspension contains:
Cephradine USP……..250mg

Otid® 250mg Capsules
Each capsule contains:
Cephradine USP……..250mg

Otid® 500mg Capsules
Each capsule contains:
Cephradine USP……..500mg

CLINICAL PHARMACOLOGY:

Otid® (Cephradine) is acid stable. It is rapidly absorbed after oral administration in the fasting state. Following single dose of 250mg, 500mg and 1g in normal adult volunteers, average peak serum concentrations within one hour were approximately 9mcg/ml, 16.5mcg/ml and 24.2mcg/ml, respectively. In vitro studies by an ultracentrifugation technique shows that at therapeutic serum antibiotic concentrations, cephradine is minimally bound (8 to 17 percent) to normal serum protein. Cephradine does not pass across the blood-brain barrier to any appreciable extent. The presence of food in the gastrointestinal tract delays absorption but does not affect the total amount of cephradine absorbed. Over 90 percent of the drug is excreted unchanged in the urine within six hours. Peak urine concentrations are approximately 1600mcg/ml, 3200mcg/ml and 4000mcg/ml following single doses of 250mg, 500mg and 1g respectively

Microbiology: In vitro tests demonstrate that the cephalosporins are bactericidal because of their inhibition of cell-wall synthesis. Cephradine is active against the following organisms in vitro:

- Group A beta-hemolytic streptococci
- Staphylococci, including coagulase-positive, coagulase-negative and penicillinase-producing strains
- Streptococcus pneumoniae (formerly Diplococcus pneumoniae)
- Escherichia coli
- Proteus mirabilis
- Klebsiella species
- Haemophilus influenzae

Cephradine is not active against most strains of Enterobacter species, P. morganii and P. vulgaris. It has no activity against Pseudomonas or Herellea species. When tested by in vitro methods, staphylococci exhibit cross-resistance between cephradine and methicillin-type antibiotics
Note: Most strains of enterococci (Streptococcus faecalis) are resistant to cephradine

INDICATIONS AND USAGE:

Otid® (Cephradine) capsules and **Otid®** for oral suspension are indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms:

- **Respiratory tract infections** (e.g., tonsillitis, pharyngitis and lobar pneumonia) caused by group A beta-hemolytic streptococci and S. pneumoniae
- **Otitis media** caused by group A beta-hemolytic streptococci, S. pneumoniae H. influenzae and staphylococci
- **Skin and skin structure infections** caused by staphylococci (penicillin-susceptible and penicillin-resistant) and beta-hemolytic streptococci
- **Urinary tract infections** including prostatitis, caused by E. coli, P. mirabilis, Klebsiella species and enterococci (S.faecalis)

Note: Culture and susceptibility tests should be initiated prior to and during therapy

CONTRAINDICATIONS:
Cephradine is contraindicated in patients with known allergy to the cephalosporin group of antibiotics or who have previously experienced a major allergy to penicillin

WARNINGS:
In penicillin-sensitive patients, cephalosporin derivatives should be used with great caution. There is clinical and laboratory evidence of partial cross-allergenicity of the penicillins and the cephalosporins and there are instances of patients who have had reactions to both drug classes (including anaphylaxis after parenteral use)

Pseudomembranous colitis has been reported with the use of cephalosporins (and other broad spectrum antibiotics); therefore, it is important to consider its diagnosis in patients who develop diarrhoea in association with antibiotic use. Treatment with broad spectrum antibiotics alters normal flora of the colon and may permit overgrowth of clostridium. Studies indicate a toxin produced by Clostridium difficile is one primary cause of antibiotic-associated colitis. Cholestyramine and Colestipol resins have been shown to bind the toxin in vitro. Mild cases of colitis may respond to drug discontinuance alone. Moderate to severe cases should be managed with fluid, electrolyte and protein supplementation as indicated. When the colitis is not relieved by drug discontinuance or when it is severe, oral vancomycin is the treatment of choice for antibiotic-associated pseudomembranous colitis produced by C. difficile. Other causes of colitis should also be considered

PRECAUTIONS:
General
Prescribing **Otid®** in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria. Patients should be followed carefully so that any side effects or unusual manifestations of drug idiosyncrasy may be detected. If a hypersensitivity reaction occurs, the drug should be discontinued and the patient treated with the usual agents, e.g., pressor amines, antihistamines or corticosteroids.
Administer cephradine with caution in the presence of markedly impaired renal function. In patients with known or suspected renal impairment, careful clinical observation and appropriate laboratory studies should be made prior to and during therapy as cephradine accumulates in the serum and tissues
Cephradine should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis. Prolonged use of antibiotics may promote the overgrowth of nonsusceptible organisms. Should superinfection occur during therapy, appropriate measures should be taken

DRUG INTERACTIONS:
When administered concurrently, the following drugs may interact with cephalosporins:

Other antibacterial agents: Bacteriostats may interfere with the bactericidal action of cephalosporins in acute infection; other agents, e.g., aminoglycosides, colistin, polymyxins, vancomycin may increase the possibility of nephrotoxicity
Diuretics (potent "loop diuretics," e.g., furosemide and ethacrynic acid): Enhanced possibility for renal toxicity
Probenecid: Increased and prolonged blood levels of cephalosporins, resulting in increased risk of nephrotoxicity
Carcinogenesis, Mutagenesis: Long-term studies in animals have not been performed to evaluate carcinogenic potential or mutagenesis
Pregnancy Category B: Reproduction studies have been performed in mice and rats at doses up to four times the maximum indicated human dose and have revealed no evidence of impaired fertility or harm to the fetus due to cephradine. 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
Nursing Mothers: Since cephradine is excreted in breast milk during lactation, caution should be exercised when cephradine is administered to a nursing woman

ADVERSE REACTIONS:
Dermatologic: Rash
Gastrointestinal: Diarrhoea, Nausea, Vomiting, Pseudomembranous colitis
Genitourinary: Vaginitis
Hematologic: Transient neutropenia, Eosinophilia, Leukopenia
Hepatic: Liver enzymes elevated, Bilirubin elevated
Neuromuscular and skeletal: Arthralgia
Renal: BUN and Serum creatinine elevated
Other adverse reactions have included dizziness and tightness in the chest and candidal vaginitis

DOSAGE AND ADMINISTRATION:
Cephradine may be given regardless to meals
Adults: For respiratory tract infections (other than lobar pneumonia) and skin and skin structure infections, the usual dose is 250mg every 6 hours or 500mg every 12 hours
For lobar pneumonia, the usual dose is 500mg every 6 hours or 1g every 12 hours
For uncomplicated urinary tract infections, the usual dose is 500mg every 12 hours. In more serious urinary tract infections, including prostatitis, 500mg every 6 hours or 1g every 12 hours may be administered
Larger doses (up to 1g every 6 hours) may be given for severe or chronic infections
Children: No adequate information is available on the efficacy of b.i.d. regimens in children under nine months of age. The usual dose in children over nine months of age is 25 to 50mg/kg/day administered in equally divided doses every 6 or 12 hours. For otitis media due to H. influenzae, doses are from 75 to 100mg/kg/day administered in equally divided doses every 6 or 12 hours, but should not exceed 4g per day. Dosage for children should not exceed dosage recommended for adults
All patients, regardless of age and weight: Larger doses (up to 1g q.i.d.) may be given for severe or chronic infections
Patients with Impaired Renal Function:
Not on Dialysis: The following initial dosage schedule is suggested as a guideline based on creatinine clearance. Further modification in the dosage schedule may be required because of individual variations in absorption:

Creatinine Clearance	Dose	Time Interval
> 20ml/min	500mg	6 hours
5-20ml/min	250mg	6 hours
< 5ml/min	250mg	12 hours

On Chronic, Intermittent Hemodialysis:

250mg Start
250mg at 12 hours
250mg 36-48 hours (after start)
Children may require dosage modification proportional to their weight and severity of infection

OR
As directed by the physician

DIRECTION FOR RECONSTITUTION:

Otid® 125mg/5ml and 250mg/5ml suspension (90ml)
Shake bottle to loosen the mass. Add one time completely filled provided cup (50ml) with freshly boiled cool water into bottle. Shake well to form uniform suspension

STABILITY:
See expiry on the pack

AVAILABILITY:
Otid® 125mg/5ml suspension in pack of 90ml
Otid® 250mg/5ml suspension in pack of 90ml
Otid® 250mg capsules in pack of 12's
Otid® 500mg capsules in pack of 12's

INSTRUCTIONS:
Keep out of reach of children.
Avoid exposure to heat, light and humidity
Store between 15 to 30°C.
Improper storage may deteriorate the medicine
The reconstituted suspension can be used within 7 days if stored at controlled room temperature (15 - 30°C) or within 14 days if stored under refrigeration (2 - 8°C)

Manufactured by:
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Associate of:
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اوٹیڈ®

سسپینشن / کیپسول

(سیفراڈین)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں
ہدایات: بچوں کی پہنچ سے دور رکھیں
دوا کو دھوپ، گرمی اور نمی سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ
کے درمیان رکھیں۔ ورنہ دوا خراب ہو جائے گی
تیار شدہ سسپینشن اگر کمرے کے درجہ حرارت (15-30°C) میں رکھا گیا ہو تو ۷ دن
تک اور ریفریجریٹر (2-8°C) میں رکھا گیا ہو تو ۱۴ دن تک استعمال کیا جا سکتا ہے

R.N-04/HA/07/2020