Cephran®

Cefradine

Description: Cefradine (**Cephran®**) is a semi-synthetic and first generation cephalosporin that can be given both by mouth and by injection. It is a broad-spectrum bactericidal antibiotic active against both gram-positive and gram-negative bacteria. It is also highly active against most strains of penicillinase producing staphylococci. It has a high degree of stability to many beta-lactamases.

Mode of action: Cefradine works by inhibiting bacterial cell wall synthesis. The final stage of peptidoglycan synthesis in the bacterial cell wall is a cross-linking reaction carried out by transpeptidase enzyme. Cefradine inhibits this transpeptidase enzyme. As a result the cell wall of the bacterium is weakened, which then swells and ruptures.

Pharmacokinetics: The oral drug is well absorbed from the small intestine by carrier mediated active transport system. Plasma concentrations of 18-25 mg/L are achieved after an oral dose of 500 mg and 24-34 mg/L after 1 gm; the peak plasma concentration being achieved around 1 hour after administration of the drug as the capsule. Serum concentrations after 5 minutes of intravenous administration were approximately 90 mg/L after 1 gm and 40 mg/L after 500 mg. The plasma half-life is 0.7-0.8 hour after oral administration and 0.3 hour after intravenous administration. Cefradine is not metabolized and has a large volume of distribution. Cefradine is excreted unchanged in urine.

Composition: Cephran® 500 mg Capsule: Each capsule contains Cefradine BP 500 mg. **Cephran® Powder for Paediatric Drops:** After reconstitution each 1.25 ml contains Cefradine BP 125 mg. **Cephran® Powder for Suspension:** After reconstitution each 5 ml contains Cefradine BP 125 mg. **Cephran® DS Powder for Suspension:** After reconstitution each 5 ml contains Cefradine BP 250 mg. **Cephran® 500 mg Injection:** Each vial contains Cefradine BP 500 mg. **Cephran® 1 gm Injection:** Each vial contains Cefradine BP 1 gm.

Indications: Upper respiratory tract infections: Pharyngitis, tonsillitis, sinusitis, otitis media, laryngo-tracheo bronchitis. Lower respiratory tract infections: Acute and chronic bronchitis, lobar pneumonia, broncho pneumonia. Urinary tract infections: Cystitis, urethritis, pyelonephritis. Skin and soft tissue infections: Abscess, cellulitis, furunculosis, impetigo. Prophylaxis for surgical procedures associated with high risk of disastrous consequences of infection. Other serious infections caused by sensitive organisms in both adults and children.

Dosage & administration: Cefradine may be given without regard to meals. Oral: Adults: For urinary tract infections the usual dose is 500 mg four times daily or 1 gm twice daily; severe or chronic infections may require larger doses. Prolonged intensive therapy is needed for complications such as prostatitis and epididymitis. For respiratory tract infections and skin and soft tissue infections, the usual dose is 500 mg four times daily or 1 gm twice daily depending on the severity and site of infections. Children: The usual dose is 25 to 50 mg/kg/day in two to four equally divided doses. For otitis media, the dose is 75 to 100 mg/kg/day in divided doses every 6 to 12 hours. Maximum dose is 4 gm per day. Deep IM/IV injection over 3-5 minutes or by IV infusion: Adults: 0.5-1 gm, 6 hourly; increased to 8 gm daily in severe infections. Children: 50-100 mg/kg daily in 4 divided doses. For surgical prophylaxis, by deep IM/IV injection over 3-5 minutes, 1-2 gm immediately prior to surgery. Renal impairment dosage: Patients not on dialysis: The following dosage schedule is suggested as a guideline based on a dosage of 500 mg per 6 hours and on creatinine clearance. Further modification in the dosage schedule may be required because of the dosage selected and individual variation.

Creatinine clearance (ml/min)	Dose	Time interval
> 20	500 mg	6 hrs
5-20	250 mg	6 hrs
< 5	250 mg	50-70 hrs

Direction for use: Cephran® DS *Powder for Suspesion:* For the suspension, shake the bottle well before adding water. Then add 60 ml (12 tea-spoonful) of boiled and cooled water to the bottle. Continue shaking the bottle gently until the powder is mixed properly. Shake the bottle well before each use. **Cephran®** *Powder for Suspension:* For the suspension, shake the bottle well before adding water. Then add 75 ml (15 tea-spoonful) of boiled and cooled water to the bottle. Continue shaking the bottle gently until the powder is mixed properly. Shake the bottle well before each use. **Cephran®** *Powder for Paediatric Drops:* Before adding water, shake the bottle well. Then add 10 ml (2 tea-spoonful) of boiled and cooled water to the bottle. Continue shaking the bottle gently until the powder is mixed properly. Shake the bottle well before each use. **Cephran®** *500 mg Injection:* Intramuscular: Add 2 ml of water for injection to 500 mg vial and shake. Intravenous: Add 5 ml of water for injection to 500 mg vial and shake. The solution should be slowly injected directly into the vein over a 3 to 5 minutes period. **Cephran®** *1 gm Injection:* Intramuscular: Add 4 ml of water for injection to 1 gm vial and shake. Intravenous: Add 10 ml of water for injection to 1 gm vial and shake. The solution should be slowly injected directly into the vein over a 3 to 5 minutes period.

Contraindications: Patients with known hypersensitivity to cephalosporins and with caution to those known to be hypersensitive to penicillin, because cross-allergy can occur. Cefradine should not be administered intrathecally.

Side effects: Hypersensitivity phenomena are more likely in patients with a history of allergy, asthma, hay fever or urticaria. Most side effects have been mild. Adverse effects have been encountered in about 7% of patients with oral cephalosporins, principally nausea and diarrhea, skin rashes and vaginitis.

Use in pregnancy & lactation: No teratogenicity has been demonstrated. Cefradine should be used during pregnancy when clearly needed. Cefradine is excreted in breast milk and should be used with caution in lactating mothers.

Precautions: In penicillin-sensitive patients, Cefradine should be used with great caution. Administer cefradine with caution in the presence of markedly impaired renal function.

Drug interactions: The cephalosporins are potentially nephrotoxic and may enhance the nephrotoxicity of aminoglycoside antibiotics, such as gentamicin and tobramycin. The nephrotoxicity of cefradine is increased by furosemide and one should be cautious about the use of any cephalosporin with furosemide and ethacrynic acid. Combinations with aminoglycosides may exert more potent bactericidal action against some organisms than used alone.

Overdosage: There are no well documented cases of overdose but severe nausea and diarrhoea would be expected. Convulsions may occur in patients receiving large doses of some cephalosporins especially in patients with renal failure.

Storage: Store in a cool (Below 25° C temperature) and dry place protected from light.

Packaging:
Cephran® 500 mg Capsule: Each carton contains 7X4 capsules in blister pack.
Cephran® Powder for Paediatric Drops: Each carton contains a bottle having dry powder to reconstitute 15 ml paediatric drops.
Cephran® Powder for Suspension: Each carton contains a bottle having dry powder to reconstitute 100 ml suspension.
Cephran® DS Powder for Suspension: Each carton contains a bottle having dry powder to reconstitute 100 ml suspension.
Cephran® 500 mg Injection: Each carton contains 4 vials with 4 ampoules of 5 ml water for injection in blister pack.
Cephran® 1 gm Injection: Each carton contains one vial with one ampoule of 10 ml water for injection in blister pack and a sterile 10 ml disposable syringe.

Opsonin Pharma
Ideas for healthcare

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