Sefur®

Cefuroxime

Description: Sefur® (Cefuroxime) is one of the bactericidal second generation cephalosporin antibiotics, which is active against a wide range of Gram-positive and Gram-negative susceptible organisms including many beta-lactamase producing strains. It is indicated for the treatment of infections caused by sensitive bacteria.

Mode of action: Sefur® (Cefuroxime) has bactericidal activity against a wide range of common pathogens, including beta-lactamase producing strains. The bactericidal action of cefuroxime is resulted from inhibition of cell wall synthesis by binding to essential target proteins.

Pharmacokinetics: After oral administration cefuroxime axetil is absorbed from the gastrointestinal tract and rapidly hydrolysed in the body to release cefuroxime into the circulation. Approximately 60% of an administered dose is absorbed. Optimum absorption occurs when it is administered after a light meal. The mean peak serum level of cefuroxime following a 250 mg dose in normal healthy adults, after food, was 4.1 mg/l and occurred two to three hours after dosing. The serum half-life after either IM or IV administration is approximately 70 minutes. After IM injection the peak serum level occurs after about 45 minutes. The blood brain barrier can be passed by cefuroxime when the meninges are inflamed. Cefuroxime is almost completely recovered unchanged in the urine within 24 hours, most being excreted within six months.

Composition: Sefur® 125 mg Tablet: Each film coated tablet contains Cefuroxime Axetil BP 150 mg equivalent to Cefuroxime 125 mg. **Sefur® 250 mg Tablet:** Each film coated tablet contains Cefuroxime Axetil BP 300 mg equivalent to Cefuroxime 250 mg. **Sefur® 500 mg Tablet:** Each film coated tablet contains Cefuroxime Axetil BP 600 mg equivalent to Cefuroxime 500 mg. **Sefur® 70 ml Granules for Suspension:** Each 5 ml reconstituted suspension Contains Cefuroxime Axetil BP 150 mg equivalent to Cefuroxime 125 mg. **Sefur® DS 50 ml Granules for Suspension:** Each 5 ml reconstituted suspension Contains Cefuroxime Axetil BP 300 mg equivalent to Cefuroxime 250 mg. **Sefur® 750 mg IM/V Injection:** Each vial contains sterile Cefuroxime Sodium BP 787.50 mg equivalent to Cefuroxime 750 mg. **Sefur® 1.5 gm IV Injection:** Each vial contains sterile Cefuroxime Sodium BP 1.575 gm equivalent to Cefuroxime 1.5 gm.

Indications: ● Pharyngitis/tonsillitis. ● Acute bacterial otitis media ● Acute bacterial maxillary sinusitis ● Lower respiratory tract infections including pneumoniae ● Acute bacterial exacerbations of chronic bronchitis and secondary bacterial infections of acute bronchitis ● Skin and Skin-Structure Infections ● Urinary tract infections ● Bone and Joint Infections ● Uncomplicated gonorrhea (urethral and endocervical) ● Early Lyme disease (erythema migrans) ● Septicemia ● Meningitis ● Surgical Prophylaxis: Prophylaxis against infections in abdominal, pelvic, orthopedic, cardiac, pulmonary, esophageal and vascular surgery where there is increased risk for infection.

Dosage And Administration: Sefur® *Tablet*: The usual course of therapy with Cefuroxime tablets is 5 to 7 days for treatment of bronchitis, and 7 to 10 days for other infections.

Adolescents and Adults (13 years and older)

Infection	Dosage	Duration (days)
Pharyngitis/tonsilitis	250 mg b.i.d.	05-10
Acute bacterial maxillary sinusitis	250 mg b.i.d.	10
Acute bacterial exacerbations of chronic bronchitis	250 or 500 mg b.i.d.	10
Secondary bacterial infections of acute bronchitis	250 or 500 mg b.i.d.	05-10
Uncomplicated skin and skin-structure infections	250 or 500 mg b.i.d.	10
Uncomplicated urinary tract infections	250 mg b.i.d.	07-10
Uncomplicated gonorrhea	1,000 mg	Single dose
Early Lyme disease	500 mg b.i.d.	20
Pediatric Patients (who can swallow tablets whole)		
Pharyngitis/tonsilitis	125 mg b.i.d.	5-10
Acute otitis media	250 mg b.i.d.	10
Acute bacterial maxillary sinusitis	250 mg b.i.d.	10
		(May be administered without regard to meals)

Sefur® Suspension: Can be administered to pediatric patients ranging in age from 3 months to 12 years. **Must be administered with food. Shake well each time before using.**

Infection	Dosage	Daily Maximum dose	Duration (days)
Pharyngitis/Tonsilitis	20 mg/kg/day b.i.d	500 mg	10
Acute otitis media	30 mg/kg/day b.i.d	1,000 mg	10
Acute bacterial maxillary sinusitis	30 mg/kg/day b.i.d	1,000 mg	10
Impetigo	30 mg/kg/day b.i.d	1,000 mg	10

Injection: Adult: 750 mg three times daily by IM or IV injection. In severe infections, dose can be increased upto 1.5 gm three times daily by IV injection. The frequency may be increased to four times daily, if necessary, giving total daily doses of 3 to 6 gms.

Children (above 3 months of age): 30 - 100 mg/kg/day given in 3 or 4 equally divided doses. A dose of 60mg/kg/day is appropriate for most infections.
Neonate: 30 - 100 mg/kg/day given in 2 or 3 equally divided doses.
Surgical prophylaxis: 1.5 gm by IV injection at induction of anaesthesia; up to 3 further doses of 750 mg may be given by IV/IM injection every 8 hours for high risk procedures.

Sequential therapy in adults: *Pneumonia:* 1.5 gm IV injection twice daily for 2-3 days, followed by 500 mg twice daily (oral) for 7-10 days. ***Acute exacerbations of chronic bronchitis:*** 750 mg twice daily (IM or IV injection) for 2-3 days, followed by 500 mg twice daily (oral) for 5-10 days. (Duration of both parenteral and oral therapy is determined by the severity of the infection and the clinical status of the patient.). **Other recommendations: *In Gonorrhoea:*** Adult: 1.5g as a single dose (as 2 x 750mg injections intramuscularly with different sites, e.g. each buttock).
In Meningitis: Adults: 3 gm IV injection three times daily. Children (above 3 months of age): 200-240 mg/kg/day by IV injection in 3 or 4 divided doses reduced to 100 mg/kg/day after 3 days or on clinical improvement. Neonate: 100 mg/kg/day by IV injection reduced to 50 mg /kg/day. ***In bone and joint infections:*** Adult: 1.5 gm IV injection four times daily. Children (above 3 months of age): 150 mg/kg/day (not to exceed the maximum adult dose) in equally divided doses every 8 hours. ***In impaired renal function:*** A reduced dose must be employed when renal function is impaired. Dosage in adults should be determined by the degree of renal impairment and the susceptibility of the causative organism according to the table below -

Creatinine clearance (ml/min)	Dose Frequency
> 20	750 mg - 1.5 gm q8h
10-20	750 mg q12h
< 10	750 mg q24h*

**Since Cefuroxime is dialyzable, patients on hemodialysis should be given a further dose at the end of the dialysis. In paediatric patients with renal insufficiency, the frequency of dosing should be modified consistent with the recommendations for adults.*

Contraindications: Patients with known allergy to cephalosporins & pseudomembranous colitis are contraindicated.

Side effects: Generally Cefuroxime is well tolerated. However, a few side effects like nausea, vomiting, diarrhea, abdominal discomfort or pain may occur. As with other broad-spectrum antibiotics, prolonged administration of Cefuroxime may result in overgrowth of nonsusceptible microorganisms. Rarely (<0.2%) renal dysfunction, anaphylaxis, angioedema, pruritis, rash and serum sickness like urticaria may appear.

Use in pregnancy & lactation: Pregnancy: While all antibiotics should be avoided in the first trimester if possible. However, Cefuroxime has been safely used in later pregnancy to treat urinary and other infections.
Nursing mothers: Cefuroxime is excreted into the breast milk in small quantities. However, the possibility of sensitizing the infant should be kept in mind.

Precautions: Cefuroxime should be given with care to patients receiving concurrent treatment with potent diuretics & who have history of colitis.

Drug Interactions: Concomitant administration of probenecid with **Sefur®** increases the area under the serum concentration versus time curve by 50%. Drug that reduces gastric acidity may result in a lower bioavailability of cefuroxime and tend to cancel the effect of postprandial absorption. In common with other antibiotics, cefuroxime axetil may affect the gut flora, leading to lower estrogen reabsorption and reduced efficacy of combined oral estrogen/progesterone.

Over dosage: Overdosage of **Sefur®** can cause cerebral irritation leading to convulsions. Serum level can be decreased by hemodialysis and peritoneal dialysis.

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

Packaging: Sefur® 125 mg Tablet: Each carton contains 6X2 tablets in Alu-Alu blister pack. **Sefur® 250 mg Tablet:** Each carton contains 7X2 tablets in Alu-Alu blister pack. **Sefur® 500 mg Tablet:** Each carton contains 7X1 tablets in Alu-Alu blister pack. **Sefur® 70 ml Granules for Suspension:** Each carton contains a bottle having granules to reconstitute 70 ml suspension. **Sefur® DS 50 ml Granules for Suspension:** Each carton contains a bottle having granules to reconstitute 50 ml suspension. **Sefur® 750 mg IM/V Injection:** Each carton contains 1 vial of Cefuroxime 750 mg as sterile Cefuroxime sodium BP with 1 ampoule of 10 ml water for injection and a 10 ml disposable syringe. **Sefur® 1.5 gm IV Injection:** Each carton contains 1 vial of Cefuroxime 1.5 gm as sterile Cefuroxime sodium BP with two ampoule of 10 ml Water for Injection USP in a blister pack and a 20 ml disposable syringe, a butterfly needle, a first aid bandage and an alcohol pad.

Opsonin Pharma
Ideas for healthcare

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