



Cefuroxime Sodium BP

**Oral Preparation****Presentation**

Sefurox 125 tablet : White, film coated, capsule shaped tablets. Each tablet contains

Cefuroxime 125mg (as Cefuroxime Axetil BP).

Sefurox 250 tablet : White, film coated, capsule shaped tablets. Each tablet contains

Cefuroxime 250mg (as Cefuroxime Axetil BP).

Sefurox 500 tablet : White, film coated, capsule shaped tablets. Each tablet contains

Cefuroxime 500mg (as Cefuroxime Axetil BP).

Sefurox suspension : Bottles containing granules for preparation of 70ml flavoured suspension.

When reconstituted each 5ml contains Cefuroxime Axetil BP equivalent to Cefuroxime 125mg (as Cefuroxime Axetil BP).

Sefurox 750 Injection: Powder in vials containing Cefuroxime Sodium BP equivalent to Cefuroxime 750mg which after reconstitution is intended for intramuscular, intravenous injection or intravenous infusion.

Sefurox 1.5 Injection: Each vial contains sterile Cefuroxime sodium BP equivalent to 1.5g Cefuroxime which after reconstitution is intended for intravenous injection or intravenous infusion.

Indications

Sefurox is a bactericidal cephalosporin antibiotic which is resistant to most beta-lactamases and is active against a wide range of Gram-positive and Gram-negative organisms.

Indications include:

Lower respiratory tract infections for example, acute and chronic bronchitis, infected bronchiectasis, bacterial pneumonia, lung abscess and post-operative chest infections.

Upper respiratory tract infections for example, ear, nose and throat infections, such as sinusitis, tonsillitis, pharyngitis and otitis media.

Urinary tract infections for example acute and chronic pyelonephritis, cystitis and asymptomatic bacteriuria.

Soft-tissue infections for example cellulitis, erysipelas and wound infections.

Bone and joint infections for example, osteomyelitis and septic arthritis.

Obstetric and gynaecological infections, pelvic inflammatory diseases.

Gonorrhoea particularly when penicillin is unsuitable.

Other infections including septicemia, meningitis and peritonitis.

Prophylaxis against infection in abdominal, pelvic, orthopedic, cardiac, pulmonary, oesophageal and vascular surgery where there is increased risk from infection.

Microbiology

Cefuroxime sodium owes its in vivo bactericidal activity to the parent compound, cefuroxime. Cefuroxime is a well-characterized and effective antibacterial agent which has broad-spectrum, bactericidal activity against a wide range of common pathogens, including beta-lactamase, and consequently is active against many ampicillin-resistant or amoxicillin-resistant strains.

The bactericidal action of cefuroxime results from inhibition of cell-wall synthesis by binding to essential target proteins.

Cefuroxime is usually active against the following organisms in vitro: Aerobic, Gram-negative: Haemophilus influenzae (including ampicillin-resistant strains); Haemophilus parainfluenzae; Moraxella catarrhalis; Escherichia coli; Klebsiella species; Proteus mirabilis; Proteus inconstans; Providencia rettgeri and Neisseria gonorrhoeae (including penicillinase-and non-penicillinase-producing strains).

Aerobic, Gram-positive: Staphylococcus aureus (including penicillinase-producing strains, but excluding methicillin-resistant strains); Staphylococcus epidermidis, Streptococcus pneumonia (and other beta-haemolytic streptococci); Streptococcus Group B (Streptococcus agalactiae) and Propionibacterium species. Certain strains of enterococci, eg. *Streptococcus faecalis* are resistant.

Anaerobes, Gram-positive and Gram-negative cocci (including *Peptococcus* and *Peptostreptococcus* species); Gram-positive bacilli (including *Clostridium* species) and Gram-negative bacilli (including *Bacteroides* and *Fusobacterium* species). Most strains of *Bacteroides fragilis* are resistant.

Pseudomonas species, Campylobacter species, Acinetobacter calcoaceticus and most strains of *Serratia* and *Proteus vulgaris* and *Clostridium difficile* are resistant to many cephalosporins including cefuroxime.

Dose and administration**Oral:****Adults**

Most infections will respond to 250mg b.i.d. In mild to moderate lower respiratory tract infections e.g. bronchitis 250mg b.i.d. should be given. For more severe lower respiratory tract infections, or if pneumonia is suspected then 500mg b.i.d. should be given. For urinary tract infections a dose of 125mg b.i.d. is usually adequate; in pyelonephritis the recommended dose is 250mg b.i.d. A single dose of 1g is recommended for the treatment of uncomplicated gonorrhoea.

Children

The usual dose is 125mg b.i.d. In children with otitis media, 250mg b.i.d. may be used. Cefuroxime Axetil BP tablets should not be crushed and are therefore unsuitable for children under 5 years of age.

No special precautions are necessary in patients with renal impairment or on renal dialysis or in the elderly at dosages up to the normal maximum of 1g per day. Cefuroxime Axetil should be taken after food for optimum absorption.

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more severe infections, this dose should be increased to 1.5g three times daily I.V. The frequency may be increased to 6-hourly if necessary, giving total daily doses of 3 to 6g.

Neonates: Doses of 30 to 100mg/kg/day given as two or three divided doses. In the first weeks of life the serum half life of cefuroxime can be three to five times that in adults.

Other recommendations:

Gonorrhoea: 1.5g as a single dose or 2x750mg injections into different sites, e.g. each buttock.

Meningitis: Sefurox is suitable for sole therapy of bacterial meningitis due to sensitive strains.

The following dosages are recommended:

Adults: 3g given intravenously every eight hours.

Infants and Children: 200-240 mg/kg/day given intravenously in 3 or 4 divided doses. This dose may be reduced to 100mg/kg/day i.v. after 3 days or when clinical improvement occurs.

Neonates: The dosage should be 100 mg/kg/day given intravenously. A reduction to 50mg/kg/day i.v. may be made when clinically indicated.

Prophylaxis: The usual dose is 1.5g given intravenously with induction of anaesthesia for abdominal, pelvic and orthopaedic operations. This may be supplemented with two 750mg intramuscular doses eight and sixteen hours later.

In cardiac, pulmonary, oesophageal and vascular operations, the usual dose is 1.5g given intravenously with induction of anaesthesia, continuing with 750mg given intramuscularly three times daily for a further 24 to 48 hours.

In total joint replacement, 1.5g Cefuroxime powder may be mixed dry with each pack of methyl methacrylate cement monomer before adding the liquid polymer.

As is the case with other antibiotics characterized by prevailing renal elimination, in order to prevent build-up effects

In cases of renal failure, we recommend that the dosage schemes listed below be followed in adult patients:

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Direction Slip artwork legend

Product Name : Sefurox

Code number : 510370/1

CDCS Version : 01

Dimension : L 14 x W 7 inches

Min. size of text : 8 pt

Used Colors : Black C Pantone 186 C

Manufactured by:
 synovia

Synovia Pharma PLC., Station Road, Tongi, Gazipur.

A Subsidiary of BEXIMCO PHARMACEUTICALS LTD.

510370/1