

**MANY-SIDED ANTIBIOTIC
FOR THERAPEUTIST, SURGEONS AND PEDIATRIST**

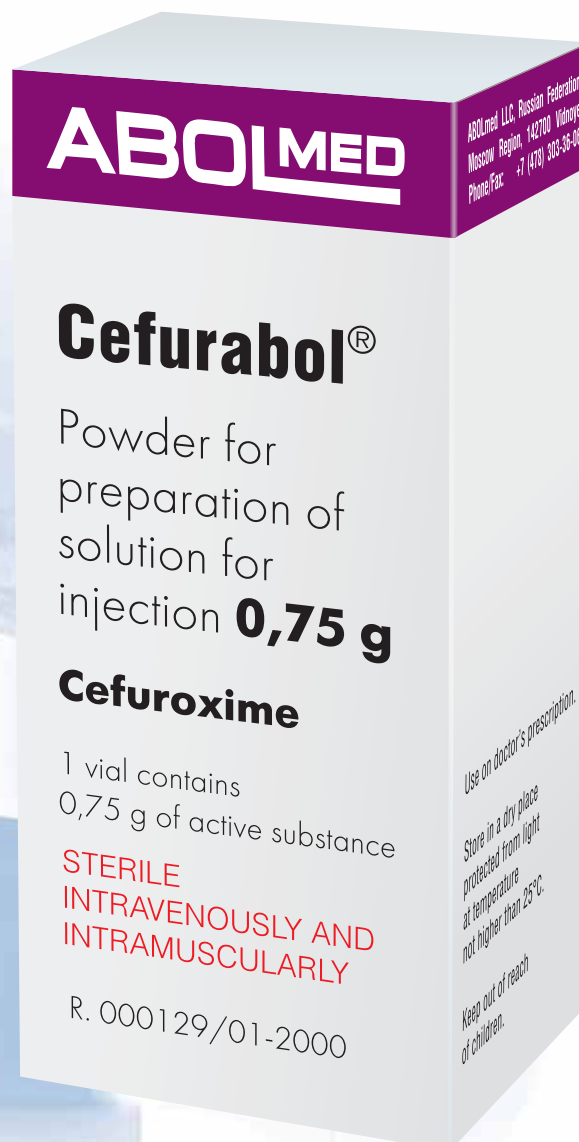
Cefurabol®

(cefuroxime)

2nd generation cephalosporin
with broad spectrum of antimicrobial activity

**Effective treatment of moderate
to severe bacterial infections:**

- meningitis
- lower respiratory tract infections, including community-acquired pneumonia, pleural empyema and lung abscesses
- intraabdominal infections, including peritonitis, intraabdominal abscesses, cholecystitis and cholangitis
- urinary tract infections
- skin and skin-structure infections
- septicemia
- uncomplicated and disseminated gonococcal infections
- bone and joint infections
- first-choice antibiotic for antibiotic prophylaxis of postoperative infections



ABOLMED
PHARMACEUTICAL COMPANY

Cefurabol®

(cefuroxime)

DESCRIPTION

Cefurabol® is a semisynthetic 2nd generation cephalosporin antibiotic for parenteral use with high bactericidal effect against a wide spectrum of Gram-positive and Gram-negative microbes (including resistant to other antibiotics) and several anaerobes. **Cefurabol®** is highly resistant to the majority of beta-lactamases of Gram-positive and Gram-negative bacteria.

SPECTRUM OF ACTIVITY

Bactericidal action of **Cefurabol®** is mediated by inhibition of microbial cell wall components synthesis. **Cefurabol®** is effective against the following microbes:

Gram-positive aerobes

S. aureus, *S. epidermidis*, *Str. pneumoniae*, *Str. pyogenes*, *Str. viridans*, *Str. agalactiae*, *Str. bovis*

Gram-negative aerobes

Aeromonas spp., *Alcaligenes* spp., *B. pertussis*, *Citrobacter* spp., *Enterobacter* spp., *E. coli*, *H. influenzae* (including ampicillin-resistant strains), *H. parainfluenzae*, *Klebsiella* spp. (including *K. pneumoniae*), *M. catarrhalis* (including ampicillin- and cephalothin-resistant strains), *M. morgani*, *N. gonorrhoeae* (including penicillinase- and non penicillinase-producing strains), *N. meningitidis*, *P. mirabilis*, *P. rettgeri*, *Salmonella* spp., *Shigella* spp.

Anaerobes

Peptococcus spp., *Peptostreptococcus* spp., *Clostridium* spp., *Bacteroides* spp., *Fusobacterium* spp.

Most strains of enterococci, methicillin-resistant staphylococci, *L. monocytogenes*, *A. calcoaceticus*, *P. vulgaris*, *P. aeruginosa*, *Pseudomonas* spp., *Campylobacter* spp., *Serratia* spp., *B. cereus*, *C. difficile* and most strains of *B. fragilis* are resistant to **Cefurabol®**.

CLINICAL PHARMACOLOGY

After intramuscular (IM) injection of a 750-mg dose of **Cefurabol®**, the mean peak serum concentration is 27 mcg/mL at approximately 45 minutes. Maximal serum concentrations of **Cefurabol®** about 50 and 100 mcg/mL can be registered in 15 min after IV doses of 750 mg and 1.5 gm, respectively. Therapeutic serum concentrations of 2 mcg/mL or more are maintained for 5.3 hours and 8 hours after IV administration of 750 mg and 1.5 g, respectively. **Cefurabol®** is approximately 50% bound to serum protein. After 45 min of IM and 15 min of IV injection **Cefurabol®** maximally saturates many organs, tissues and fluids. High (therapeutic) concentrations which are much more than killing ones for pathogens can be determined in lungs, pleural fluid and sputum, synovial fluid, in bones and joints, in bile, in skin and soft tissues, in aqueous humor. Cefuroxime is detectable in therapeutic concentrations in cerebrospinal fluid (CSF) of adults and pediatric patients with meningitis. Permeates well through placenta and is present in breast milk. The serum half-life after either IM or IV injections is approximately 80 minutes. **Cefurabol®** undergoes no transformation. Approximately 89% of a dose of cefuroxime is excreted by the kidneys over an 8-hour period, resulting in high urinary concentrations.

INDICATIONS AND USAGE

Cefurabol® is indicated for the treatment of moderate to severe infections caused by susceptible strains of the microorganisms in the diseases listed below: lower respiratory tract infections, including community-acquired pneumonia, pleural empyema and lung abscesses; uncomplicated and complicated intraabdominal infections, including peritonitis, intraabdominal abscesses, cholecystitis and cholangitis; urinary tract infections; skin and skin-structure infections, including post-surgery infectious wound complications; septicemia caused by Gram-positive cocci and susceptible strains of *Enterobacteriaceae*; meningitis caused by pneumococci, *H. influenzae* (including ampicillin-resistant strains), *N. meningitidis*, and *S. aureus* (penicillinase- and non penicillinase-producing strains); uncomplicated and disseminated gonococcal infections in both males and females; bone and joint infections.

Cefurabol® can be administered as monotherapy but also in combination with antibiotics of other groups (e.g. aminoglycosides, metronidazole, vancomycin). **Cefurabol®** and aminoglycosides are synergists in antibacterial effect against Gram-negative microbes (although the risk of aminoglycoside nephrotoxicity increases).

The preoperative prophylactic administration of **Cefurabol®** may reduce the incidence of certain postoperative infections in patients undergoing clean-contaminated, potentially contaminated surgical procedures or in surgical patients in whom infections at the operative site would present a serious risk (e.g., vaginal hysterectomy, cholecystectomy, stomach resection, open heart surgery, arthroplasty).

CONTRAINDICATIONS

Hypersensitivity to cefuroxime or the cephalosporin class of antibiotics.

PRECAUTION

Pregnancy Category B. This drug should be used during pregnancy only if clearly needed. Caution should be exercised when **Cefurabol®** is administered to a nursing woman.

Cefurabol® should be given cautiously to penicillin-sensitive patients.

DRUG INTERACTIONS

«Loop» diuretics such as furosemid or ethacrynic acid being administered simultaneously are blocking tubular excretion of **Cefurabol®** which increases its concentrations and prolongs its half-elimination period. Solutions of **Cefurabol®** must not be admixed with aminoglycoside solutions. If **Cefurabol®** and aminoglycosides are to be administered to the same patient, they must be administered separately and not as a mixed injection.

ADVERSE EFFECTS

Cefurabol® is generally well tolerated. Adverse reactions are infrequent and include: local reactions (phlebitis, pain and/or inflammation); hypersensitivity (urticaria, rash, pruritus, drug fever, headache, or a change in Coombs' test); diarrhea, nausea and vomiting; mild transient elevations of liver function, transient elevations of the BUN and serum creatinine; reversible neutropenia, slight decreases in neutrophil count, WBC, platelets, hemoglobins or hematocrits and transient eosinophilia; triggering seizures (particularly in patients with renal impairment when the dosage was not reduced).

DOSAGE AND ADMINISTRATION

Cefurabol® can be administered intravenously (by slow bolus injection of 4-5 minutes duration or by infusion of not less than 30 minutes duration) or intramuscularly which depends of patient's condition and age.

Adults: The usual adult dose is 750 mg every 8 hours. In non-complicated infections of urinary tract, skin and soft tissues, disseminated gonococcal infections, non-complicated community-acquired pneumonia, a 750 mg dose of **Cefurabol®** is administered every 8 h. In severe and complicated cases as bone and joint infections, a 1.5 grams dose administered IV should be given at 8 hours interval. In life-threatening infections or infections due to less susceptible organisms, 1.5 grams administered IV every 6 hours may be required. In bacterial meningitis, the dosage should not exceed 3 grams every 8 hours. In uncomplicated gonococcal infection, 1.5 grams given intramuscularly as a single dose with 1 gram of oral probenecid or two 750 mg dose administered simultaneously at 2 different sites with 1 gram of oral probenecid is recommended.

In newborns, premature children and infants younger than 1 month old, the daily dose is 50 to 100 mg/kg divided into 2-3 injections. In children older than 1 month old, the daily dose is 50-100 mg/kg divided into 3 injections. In bacterial meningitis, the daily dose is 200 to 240 mg/kg divided into 3-4 injections. Because renal excretion is the main route of elimination of cefuroxime, patients with renal failure require adjustment in dosage.

DOSAGES IN PATIENTS WITH RENAL IMPAIRMENT

Creatinine clearance >50 mL/min	Creatinine clearance 10-50 mL/min	Creatinine clearance <10 mL/min
100%* q8h	50%-100% q12h	50% q24h

* - per cent refers to % change from dose for normal renal function

For perioperative antibiotic prophylaxis, a 1.5-gram dose administered intravenously one-half hour before the initial incision is recommended. The dose should be repeated intraoperatively if the surgical procedure is lengthy. If necessary, 750 mg is given intravenously or intramuscularly every 8 hours for 24 hours postoperatively.

In open heart surgery, a 1.5-gram dose administered intravenously during induction of anesthesia and then every 12 h for a total of 6 grams is recommended. In colorectal surgery, **Cefurabol®** should be combined with IV metronidazole or other drug from 5-nitroimidazole group.

HOW SUPPLIED

Cefurabol® is available in sterile dry powder form in vials containing sterile cefuroxime sodium equivalent to either 0.75 gm or 1.5 gm of cefuroxime for intramuscular and intravenous administration (package of 50 vials). Store for 2 years at or below a room temperature of 25°C (77°F).

Cefurabol® is manufactured by ABOLMED Ltd., Russia