

BALANCED ACTIVITY SPECTRUM

Cefamabol®

(cefamandole)

2nd generation parenteral cephalosporin



Equal activity against Gram-positive and Gram-negative aerobes and effective treatment of moderate to severe bacterial infections:

- lower respiratory infections, including pneumonia, lung abscesses, pleural empyema
- urinary tract infections, including non-complicated and complicated pyelonephritis, pyelitis
- non-complicated and complicated intra-abdominal infections including cholecystitis, cholangitis, peritonitis
- skin and skin structure infections
- bone and joint infections
- infections of ear, nose, throat, including sinusitis and otitis media
- pelvic inflammatory disease (PID)
- widely-used antibiotic for perioperative antibiotic prophylaxis

ABOLMED
PHARMACEUTICAL COMPANY

Cefamabol®

(cefamandole)

PHARMACOLOGICAL ACTION

Cefamabol® (cefamandole nafate) is a semisynthetic broad-spectrum 2nd generation cephalosporin antibiotic for parenteral administration. Resistant to many beta-lactamases produced by Gram-positive and Gram-negative microbes.

SPECTRUM OF ACTIVITY

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

Gram-positive aerobes

beta-hemolytic and other strains of streptococci including *S. pneumoniae* (many strains of *E. faecalis* are resistant), staphylococci, both penicillin-resistant and sensitive, including *S. epidermidis*

Gram-negative aerobes

H. influenzae including ampicillin-resistant strains, *E. coli*, *Enterobacter* spp. (many strains of *E. cloacae* are resistant), *K. pneumoniae*, *P. mirabilis*, indole-positive *Proteus* spp., including *P. morganii*, *P. rettgeri* and some strains of *P. vulgaris*, *Salmonella* spp., *Serratia* spp. (many strains of *S. marcescens* and other *Serratia* spp. are resistant)

Anaerobic Organisms

Clostridia spp., peptococci, peptostreptococci, some strains of *Bacteroides* spp.

Resistant to **Cefamabol®**: *Enterococcus* spp., *L. monocytogenes*, *M. tuberculosis*, *P. aeruginosa*, *Pseudomonas* spp., the majority of *E. cloacae* strains, *Chlamydia* spp., *Mycoplasma* spp.

CLINICAL PHARMACOLOGY

Cefamabol® can be quickly found in high (therapeutically significant) concentrations in serum and many organs, tissues and fluids, including lungs, pleural fluid, skin and soft tissues, kidneys, bile and gallbladder wall, abdominal organs, peritoneal and synovial fluid and bones. Penetrates into cerebrospinal fluid insufficiently (CSF concentrations are insufficient for bactericidal effect even in meningitis). Permeates well through placenta. Insignificantly **Cefamabol®** is excreted with breast milk. The half-life after an intravenous dose is 32 minutes; after intramuscular administration, the half-life is 60 minutes. Sixty-five percent to 85% of cefamandole is excreted by the kidneys over an 8-hour period, resulting in high urinary concentrations.

INDICATIONS

Cefamabol® is indicated for the treatment of moderate to severe infections caused by susceptible strains of the microorganisms in the diseases listed below: lower respiratory infections, including pneumonia, lung abscesses, pleural empyema; urinary tract infections, including non-complicated and complicated pyelonephritis, pyelitis, post-surgery urinary tract infections; non-complicated and complicated intra-abdominal infections including cholecystitis, cholangitis, peritonitis; septicemia; skin and skin structure infections; bone and joint infections; infections of ear, nose, throat, including sinusitis and otitis media; pelvic inflammatory disease in females.

To reduce the incidence of certain postoperative infections in patients undergoing contaminated or potentially contaminated surgical procedures (e.g., gastrointestinal surgery, cesarean section, vaginal hysterectomy, or cholecystectomy in high-risk patients) **Cefamabol®** may be administered perioperatively. In cardiovascular surgery, neurosurgery, or prosthetic arthroplasty, **Cefamabol®** may be effective in preventing post-surgery infectious complications.

CONTRAINDICATIONS:

Hypersensitivity to cefamandole or the cephalosporin class of antibiotics, newborns younger than 3 months old.

PRECAUTION

Administration with precautions — in patients with the history of hypersensitivity to penicillin or other beta-lactam antibiotics, in lactating women, in

patients with renal impairment (dosage regimen should be corrected, see the table below), in patients with hypoprotrombinemia and coagulation disorders. *Pregnancy Category B*. Caution should be exercised when **Cefamabol®** is administered to a nursing woman.

DRUG INTERACTION

The effect of anticoagulants increases (hypoprotrombinemia). «Loop» diuretics such as furosemid or ethacrynic acid block tubular excretion of **Cefamabol®**. **Cefamabol®** inhibits acetaldehyde-dehydrogenase thus it is incompatible with alcohol. Concomitant administration with non-steroidal anti-inflammatory drugs and thrombolytics may increase the risk of bleeding.

ADVERSE EFFECTS:

Local reactions (pain on injection area, thrombophlebitis), nausea, vomiting, hypersensitivity (anaphylaxis, maculopapular rash, urticaria, eosinophilia, drug fever), thrombocytopenia, positive direct Coombs' tests during treatment, neutropenia, transient elevation in SGOT, SGPT, and alkaline phosphatase levels, mild increase in serum creatinine, transitory elevations of BUN.

DOSAGE AND ADMINISTRATION

In adults with moderate infections, 0.5-1 g IM or IV every 6-8 hours is recommended. In severe infections, the dose is increased up to 1-2 g every 4 hours (6 times a day). In life-threatening conditions such as bacterial septicemia, 6 to 12 g/day may be given initially by the intravenous route for several days, then dosage may be reduced according to clinical response and laboratory findings.

In pediatric patients (3 months of age and older) average daily dose is 50 to 100 mg/kg/day in equally divided doses every 4 to 8 hours; in severe infections it is increased up to 150 mg/kg. Treatment duration is usually no longer than 10 days. A minimum of 10 days of treatment is recommended in infections caused by group A (beta)-hemolytic streptococci.

Cefamabol® may be given intravenously or by deep intramuscular injection into a large muscle mass (such as the gluteus or lateral part of the thigh) to minimize pain.

For prevention of infectious complications in post-operative period in adults: administration of 1 or 2 g intravenously 30 min prior to the surgical incision followed by 1 or 2 g every 6-8 hours for 24 to 48 hours are recommended. *In children* (3 months of age and older), administration of 20 or 30 mg/kg intravenously 30 min prior to the surgical incision followed by 20 or 30 mg/kg 6-8 hours for 24 to 48 hours are recommended.

In patients with renal impairment the dosage regimen depends on creatinine clearance value. After an initial dose of 1 to 2 g (depending on the severity of infection), a maintenance dosage schedule should be followed (see the table):

DOSAGES IN PATIENTS WITH RENAL IMPAIRMENT

Creatinine clearance, mL/min			
> 80	80-50	50-10	< 10
1-2gm q4-6h	1.5-2 gm q6h	1-1.5gm q6-8h	0,5-1gm q12h

In patients being under hemodialysis, 1 g of the drug is administered IV each 24 h after dialysis.

HOW SUPPLIED

Cefamabol® is available in sterile dry powder form in vials containing sterile cefamandole nafate equivalent to either 0.5 g or 1 g of cefamandole for intramuscular and intravenous administration (package of 50 vials).

Store for 2 years at or below a room temperature of 25°C (77°F).

Cefamabol® is manufactured by ABOLMED Ltd., Russia