

**NO! — TO POST-SURGICAL COMPLICATIONS**

# Nacef®

(cefazolin sodium)

1st generation cephalosporin  
with excellent activity against  
Gram-positive cocci



**Effective in moderate to severe infections caused by Gram-positive aerobic cocci and some *Enterobacteriaceae*:**

- skin and skin structure infections
- bone and joint infections
- septicemia
- endocarditis
- respiratory tract infections
- urinary tract infections
- biliary tract infections
- first-choice antibiotic for rational antibiotic prophylaxis of post-surgical infections

**ABOLMED**  
PHARMACEUTICAL COMPANY

# Nacef®

(cefazolin sodium)

## DESCRIPTION

**Nacef®** (cefazolin sodium) is a semi synthetic first-group cephalosporin for parenteral administration with high bactericidal effect against a wide spectrum of Gram-positive and some Gram-negative aerobes as well as several anaerobes, including penicillinase-producing strains.

## SPECTRUM OF ACTIVITY

Bactericidal action of **Nacef®** results from inhibition of cell wall synthesis. Cefazolin has been shown to be active against most strains of the following microorganisms:

### Gram-positive aerobes:

*S. aureus* (including beta-lactamase-producing strains), *S. epidermidis*, *Str. pneumoniae*, *Str. pyogenes*, *Str. agalactiae* and other strains of streptococci.

Methicillin-resistant staphylococci and many strains of enterococci are resistant to cefazolin;

### Gram-negative aerobes: *E. coli*, *P. mirabilis*;

**Anaerobes:** *Cl. perfringens*, *Peptococcus* spp., *Peptostreptococcus* spp.

### Resistant to Nacef®:

*H. influenzae*, *Enterococcus* spp., *L. monocytogenes*, *M. catharralis*, *M. tuberculosis*, *Neisseria* spp., most strains of indole-positive *Proteus* (*P. vulgaris*), *Enterobacter* spp., *M. morgani*, *P. rettgeri*, *Serratia* spp., *Pseudomonas* spp., *Salmonella* spp., *Shigella* spp. and the majority of anaerobes (including *B. fragilis*), *Chlamydia* spp., *Mycoplasma* spp.

## CLINICAL PHARMACOLOGY

After 1-2 h of intramuscular and 0.1 h of intravenous injection cefazolin sodium can be quickly found in high (therapeutically significant) concentrations in serum and many human organs, tissues and fluids, including lungs, tonsils, cardiovascular system tissues, in skin and soft tissues, in kidneys and urine tract tissues, in bile and gallbladder wall, in appendix, middle ear, synovia, bones and eye tissues. The antibiotic concentration in bile and gallbladder wall is much higher than in serum. Into cerebrospinal fluid cefazolin penetrates insufficiently (even in meningitis).

**Nacef®** transfers across the placenta promptly. **Nacef®** is excreted in the milk of nursing mothers in very low concentrations. The serum half-life for **Nacef®** is approximately 1.8 hours following IV administration and approximately 2.0 hours following IM administration. No biotransformation is observed for cefazolin. 70-80% of injected dose is excreted with urine within 24 h.

## INDICATIONS AND USAGE

**Nacef®** is indicated in the treatment of the following infections due to susceptible organisms: **skin and skin structure infections caused by Gram-positive cocci**; **bone and joint infections caused by Gram-positive cocci**; **septicemia** caused by susceptible strains of *E. coli*, *P. mirabilis*, *S. aureus*; **endocarditis** caused by *S. aureus* (including beta-lactamase-producing strains) and *S. pyogenes*; **respiratory tract infections** caused by streptococci, *S. aureus* (including beta-lactamase-producing strains); **urinary tract infections** caused by susceptible strains of *E. coli*, *P. mirabilis*; **biliary tract infections** caused by susceptible strains of *E. coli*, *P. mirabilis*, *S. aureus*; **genital infections** (incl. epididymitis) caused by susceptible strains of *E. coli*, *P. mirabilis*.

The prophylactic administration of **Nacef®** perioperatively may reduce the incidence of certain postoperative infections in patients undergoing different types of surgical procedures (vaginal hysterectomy, cholecystectomy, stomach resection, open-heart surgery, neurosurgery, traumatology, ophthalmology and prosthetic arthroplasty).

## CONTRAINDICATIONS

**Nacef®** is contraindicated in patients who have shown immediate hypersensitivity reactions to cefazolin or the cephalosporin class of antibiotics.

## PRECAUTION

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

**Drug Interactions:** increased nephrotoxicity has been reported following concomitant administration of cephalosporins and aminoglycoside antibiotics, cephalosporins with potent diuretics such as furosemide. «Loop» diuretics such as furosemid or ethacrynic acid are blocking tubular excretion of cefazolin sodium.

## ADVERSE REACTIONS

Adverse effects are relatively rare and quickly disappear after the drug withdrawal. The following reactions have been reported: diarrhea, oral candidiasis, vomiting, nausea, stomach cramps, nausea and vomiting; anaphylaxis, eosinophilia; itching, drug fever, skin rash, Stevens-Johnson syndrome; neutropenia, leukopenia, thrombocytopenia, thrombocytopenia; transient rise in SGOT, SGPT, and alkaline phosphatase; transient elevations of the BUN and serum creatinine; local reactions (phlebitis, pain and/or inflammation at the site of injection).

## DOSE AND ADMINISTRATION

**In adults with moderate infections** usual dose of **Nacef®** is 0.5-1 g every 6 to 8 hrs. In severe infections, the daily dose is increased up to 6-8 g divided into 3-4 injections (1-2 gm q6h). In the most severe cases, the maximal daily dose of **Nacef®** is 12 g. **In newborns and premature children younger than 1 week old**, the daily dose of 40 mg/kg is divided into 2 IV injections. **In newborns 2-4 week old**, the daily dose of 60 mg/kg is divided into 3 IV injections. **In children** the average daily dose is 20-50 mg/kg of body weight Total daily dosage may be increased to 100 mg per kg of body weight for severe infections. The daily dose is administered as 3-4 IV or IM injections a day. Treatment duration is usually no longer than 10 days.

**For prevention of post-surgical infectious complications** **Nacef®** is usually administered (better IV) as follows: 0.5-1 g 30 minutes prior to the start of surgery and then 500 mg to 1 gram IV or IM every 6 to 8 hours for 24 hours postoperatively, if it is necessary.

**In adult patients with renal impairment** the dosage regimen depends on creatinine clearance (see the table). The initial loading dose of **Nacef®** should be the same as in patients with normal renal function.

### DOSAGES IN PATIENTS WITH RENAL IMPAIRMENT

Clcreat >50 mL/min	Clcreat 10-50 mL/min	Clcreat <10 mL/min
1-2gm q8h	0.5-1gm q8-12h	0.5-1gm q18-24h

In pediatric patients with mild to moderate renal impairment (Clcreat of 80 to 50 mL/min.), 60 percent of the normal daily dose given in equally divided doses every 12 hours should be sufficient. In patients with moderate impairment (Clcreat of 50 to 10 mL/min.), 25 percent of the normal daily dose given in equally divided doses every 12 hours should be adequate. Pediatric patients with severe renal impairment (Clcreat of < 10mL/min.) may be given 10 percent of the normal daily dose every 24 hours. All dosage recommendations apply after an initial loading dose.

## HOW SUPPLIED

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

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

**Nacef®** is manufactured by ABOLMED Ltd., Russia