

**LOGICAL SUPPLEMENT  
TO MEDICAL EXPERIENCE AND PROFICIENCY**

# Maxycef® (cefepime)

4th generation cephalosporin  
with broad spectrum of antibacterial activity



**Extended bactericidal power for rational therapy  
of moderate to life-threatening bacterial infections:**

- **lower respiratory tract infections (community-acquired and nosocomial pneumonia, including ventilator-associated pneumonia)**
- **empiric monotherapy for febrile neutropenic patients**
- **complicated intra-abdominal infections, including pancreatogenic sepsis**
- **uncomplicated and complicated urinary tract infections**
- **moderate to severe skin and skin structure infections**
- **bone and joint infections**
- **empiric therapy of sepsis**

**ABOLMED**  
PHARMACEUTICAL COMPANY

# Maxycef®

(cefepime)

## DESCRIPTION

**Maxycef®** (cefepime hydrochloride) is a semisynthetic, broad spectrum, group IV cephalosporin antibiotic for parenteral administration. **Maxycef®** has wide spectrum of activity against many Gram-positive and Gram-negative microorganisms, good pharmacokinetics, established clinical efficacy and high tolerability.

## CLINICAL PHARMACOLOGY

Following intramuscular (IM) administration, cefepime is completely absorbed. **Maxycef®** in detectable bactericidal concentration passes into most tissues, organs, and body fluids: skin, subcutaneous adipose tissue, muscles, lung tissue, bronchial mucosa, bile, guts, peritoneum fluids, prostate. The serum protein binding of cefepime is approximately 20% and is independent of its concentration in serum. **Maxycef®** crosses the inflamed blood-brain barrier. Cefepime is excreted in human milk in very low concentration. Elimination of cefepime is principally via renal excretion with an average half-life of 2.0 hours.

## SPECTRUM OF ACTIVITY

**Maxycef®** is a bactericidal agent that acts by inhibition of bacterial cell wall synthesis. The molecular targets of cefepime are the penicillin binding proteins (PBP). **Maxycef®** has a broad spectrum of in vitro activity that encompasses a wide range of Gram-positive and Gram-negative bacteria. **Maxycef®** has a low affinity for chromosomally-encoded beta-lactamases. **Maxycef®** is highly resistant to hydrolysis by most beta-lactamases (including some EBSL) and exhibits rapid penetration into Gram-negative bacterial cells. Cefepime demonstrates bactericidal activity against most strains of the following microorganisms:

### Gram-positive aerobic cocci

*Str. pneumoniae*, groups A, B, C, D, G and F streptococci, *Str. viridans*, methicillin-sensitive *Staphylococcus* spp.

### Gram-negative aerobic bacteria

*E. coli*, *Salmonella* spp., *Shigella* spp., *Proteus* spp., *Providencia* spp., *Klebsiella* spp., *Citrobacter* spp., *Acinetobacter calcoaceticus*, *Enterobacter aerogenes*, *Serratia* spp., *Neisseria* spp., *Moraxella catarrhalis*, *H. influenzae*

### Anaerobic Microorganisms

*Peptostreptococcus* spp., *Cl. perfringens*, *Propionibacterium* spp., *Lactobacillus* spp.

Most strains of enterococci, eg, *E. faecalis*, methicillin-resistant staphylococci, *Stenotrophomonas* (formerly *Xanthomonas*) *maltophilia* and *Cl. difficile* are resistant to **Maxycef®**.

## INDICATIONS AND USAGE

**Maxycef®** is indicated in the treatment of moderate to severe infections in different localization caused by susceptible strains of the microorganisms: moderate to severe community-acquired and nosocomial pneumonia, including ventilator-associated pneumonia in ICU patients, caused by *Streptococcus pneumoniae*, *P. aeruginosa*, *K. pneumoniae*, or *Enterobacter* species; empiric monotherapy for febrile neutropenic patients; complicated intra-abdominal infections (used in combination with metronidazole), including post-surgery peritonitis; uncomplicated and complicated urinary tract infections (including pyelonephritis, post-surgery and post-procedures UTI); moderate to severe skin, skin structure bone and joint infections (including post-surgery infectious complication, infections of burn wounds); septicemia. **Maxycef®** is antibiotic of choice in moderate to life-threatening bacterial infections caused by poly-resistant nosocomial pathogens.

## CONTRAINDICATIONS

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

## PRECAUTION

**Pregnancy Category B.** Caution should be exercised when **Maxycef®** is administered to a nursing woman.

**Pediatric Use:** safety and effectiveness in pediatric patients below the age of 2 months have not been established. **Maxycef®** can be used as alter-

native antimicrobial agent in pediatric patients under 2 months of age for the treatment of serious meningitis (mainly where the suspected or proven pathogen is *Haemophilus influenzae* type b) or septicemia.

**Drug Interactions:** increased nephrotoxicity has been reported following concomitant administration of cephalosporins and aminoglycoside antibiotics, cephalosporins with potent diuretics such as furosemide.

## ADVERSE REACTIONS

**Maxycef®** 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.

## DOSAGE AND ADMINISTRATION

### Adults

The usual adult dosage range is 1 gram to 2 grams every 12 hours administered IM or IV. Dosage should be determined by susceptibility of the causative organisms, severity of infection, and the condition of the patient. Dosage for neutropenic patients is 2 g IV every 8 hours.

### Pediatric Patients (2 months up to 16 years)

The recommended dosage in pediatric patients is 50 mg/kg of body weight per day divided into two equal doses. The higher dosages should be used for more severe or serious infections (50 mg/kg/dose, q8h for febrile neutropenic patients).

**For Intravenous Infusion,** constitute the 500 mg or 1 g vial, and add an appropriate quantity of the resulting solution to an IV container with one of the compatible IV fluids (100mL 0.9% sodium chloride injection, 5% and 10% dextrose injection, 5% dextrose and 0.9% sodium chloride injection, lactated Ringers and 5% dextrose injection). The resulting solution should be administered over approximately 30 minutes.

**Intramuscular Administration:** For IM administration, **Maxycef®** should be constituted with one of the following diluents: sterile water for Injection, 0.9% sodium chloride, 5% dextrose injection, 0.5% or 1.0% lidocaine hydrochloride, or sterile bacteriostatic water for injection.

Because renal excretion is the main route of elimination of cefepime, patients with renal failure require adjustment in dosage (see the table). But the recommended initial dose of **Maxycef®** should be the same as in patients with normal renal function except in patients undergoing hemodialysis.

### DOSAGES IN PATIENTS WITH RENAL IMPAIRMENT

Creatinine clearance, (mL/min)	Recommended Maintenance Schedule			
	0.5 g q24h	1 g q12h	2 g q12h	2 g q8h
Normal	0.5 g q24h	1 g q12h	2 g q12h	2 g q8h
> 60	0.5 g q24h	1 g q12h	2 g q12h	2 g q8h
60-30	0.5 g q24h	1 g q24h	2 g q24h	2 g q12h
30-15	0.5 g q24h	0.5 g q24h	1 g q24h	2 g q24h
<15	0.25 g q24h	0.25 g q24h	0.5 g q24h	1 g q24h
Hemodialysis*	1 g on day 1, then 0.5 g q24h thereafter			1 g q24h

\* - cefepime should be administered after hemodialysis

In patients undergoing continuous ambulatory peritoneal dialysis, **Maxycef®** may be administered at normally recommended doses at a dosage interval of every 48 hours.

## HOW SUPPLIED

**Maxycef®** is available in sterile dry powder form in vials containing sterile cefepime hydrochloride equivalent to either 500 mg or 1 g of cefepime for intramuscular and intravenous administration (package of 50 vials). Store for 2 years at or below a room temperature of 25°C (77°F).

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