

## WIN A VICTORY OVER PSEUDOMONAL INFECTION

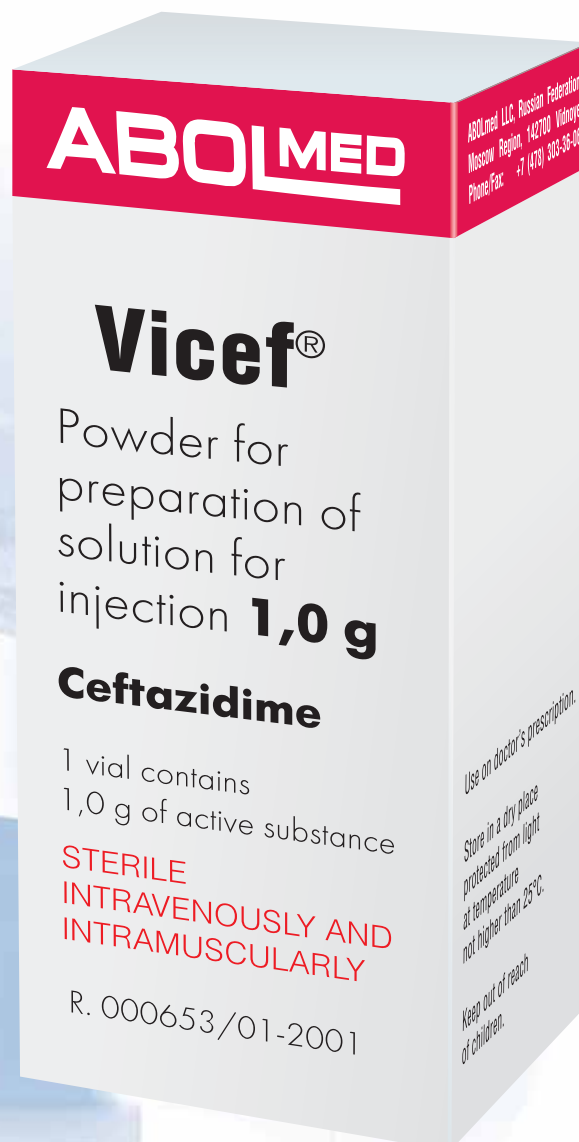
# Vicef®

(ceftazidime)

3rd generation cephalosporin with high activity against *P.aeruginosa* and wide range of Gram-negative aerobes

**First-choice antibiotic effective therapy of infections caused by *P.aeruginosa* and other Gram-negative aerobic bacteria:**

- moderate to severe respiratory tract infections, including nosocomial pneumonia and ventilator-associated pneumonia (VAP)
- severe infections of ear, nose and throat
- intraabdominal infections, including community-acquired secondary and post-operative peritonitis
- pelvic inflammatory disease, endometritis, and other infections of female genital tract
- complicated forms of urinary tract infections
- infections of the skin and skin structures including invasive burn wound infection
- bone and joint infections caused by resistant mixed microflora
- sepsis
- infections in immunocompromised patients, including febrile neutropenia



**ABOLMED**  
PHARMACEUTICAL COMPANY

# Vicef®

## (ceftazidime)

### DESCRIPTION

**Vicef®** (ceftazidime) is a sterile, semisynthetic, 3 generation parenteral cephalosporin antibiotic with high bactericidal effect against a wide spectrum of Gram-negative aerobes (including majority of *Ps. aeruginosa* strains) which are resistant to other cephalosporins. It is less active against Gram-positive aerobes than ceftriaxone and cefotaxime.

### CLINICAL PHARMACOLOGY

After IV and IM administration **Vicef®** quickly penetrates into practically all human organs, tissues and fluids. The extent of its penetration into CSF significantly increases in case of meningitis. Maximal serum concentrations of **Vicef®** can be registered in 30 min after IV injection and in 1 h after IM administration. High therapeutic drug levels could be determined during 8-12 hours after injection: in serum, peritoneal, synovial, pleural and intraocular fluids, urine, kidneys, skin, myometrium, lung tissue, sputum, cardiac tissues, tonsils, mucous membrane of nasal sinuses, uterus, bones and joints, in umbilical blood and amniotic fluid. Penetrates well through placenta. Concentrations in breast milk are low. Protein-binding of **Vicef®** with serum proteins is 10%. It does not displace bilirubin from complex with serum proteins. **Vicef®** does not metabolize in human organism. **Vicef®** is excreted from organism almost exclusively by kidneys with glomerular filtration mechanism into urine (90% of administered dose in 24 h). Thus high concentrations of **Vicef®** could be found in urine after injection. Half-elimination period (T<sub>1/2</sub>) is 1.9 h in case of IV administration and 2 h in case of IM injection. Ceftazidime T<sub>1/2</sub> period in tissues is longer than in blood.

### SPECTRUM OF ACTIVITY

Bactericidal action of **Vicef®** is mediated by inhibition of microbial cell wall components synthesis. A wide range of pathogenic strains and isolates associated with hospital-acquired infections are susceptible to ceftazidime, including strains resistant to aminoglycosides. **Vicef®** is active against:

#### Gram-positive aerobes

*S. aureus* and *S. epidermidis* (methicillin-sensitive strains), *Str. pyogenes*, group B beta-hemolytic streptococci, *Str. pneumoniae*, *Str. mitis*, *Streptococcus* spp. (excluding enterococci)

#### Gram-negative aerobes

*P. aeruginosa*, *Pseudomonas* spp., *B. cepacia*, *K. pneumoniae*, *Klebsiella* spp (other), *P. mirabilis*, *P. vulgaris*, *M. morgani*, *P. rettgeri*, *Providencia* spp., *E. coli*, *Enterobacter* spp., *Citrobacter* spp., *Serratia* spp., *Salmonella* spp, *Shigella* spp., *Y. enterocolitica*, *P. multocida*, *Acinetobacter* spp., *N. gonorrhoeae*, *N. meningitidis*, *H. influenzae* and *H. parainfluenzae* (including ampicillin-resistant strains)

#### Anaerobes

*Peptococcus* spp., *Peptostreptococcus* spp., *Clostridium* spp. (except *C. difficile*), *Bacteroides* spp., *Fusobacterium* spp.

**Vicef®** is inactive against methicillin-resistant staphylococci, *E. faecalis* and many other enterococci, *L. monocytogenes*, *Campylobacter* spp, *C. difficile*, *Mycoplasma* spp., *Chlamidia* spp., *Mycobacterium* spp., many strains of *B. fragilis*.

### INDICATIONS

**Vicef®** is strongly indicated for the treatment of the severe and some moderate nosocomial and community-acquired bacterial infections, including infections in immunocompromised patients, caused by susceptible microbes: moderate to severe respiratory tract infections, including nosocomial pneumonia, ventilator-associated pneumonia (VAP), aspiration pneumonia, pleural empyema and lung abscesses; severe infections of ear, nose and throat caused by *P. aeruginosa* and other poly-resistant Gram-negative bacteria (acute sinusitis, otitis media, malignant otitis externa); intraabdominal infections, including community-acquired secondary and post-operative peritonitis; pelvic inflammatory disease, endometritis, and other infections of the female genital tract; complicated forms of urinary tract infections, including post-surgery infections; infections of the skin and skin structures, bone and joint caused by poly-resistant mixed microflora, including diabetic foot infection, surgical site infections, invasive burn wound infection; septicemia; infections in patients with granulocytopenia, including febrile neutropenia; infections associated with hemo- and peritoneal dialysis and with continuous peritoneal dialysis (CAPD).

**Vicef®** could be administered as monotherapy and in combination with various antibiotics (aminoglycosides, metronidazole, fluorquinolones, glycopeptides).

### CONTRAINDICATIONS

**Vicef®** is contraindicated in patients who have shown hypersensitivity to ceftazidime and the cephalosporin group of antibiotics.

### PRECAUTION

**Pregnancy Category B.** This drug should be used during pregnancy only if clearly needed. Caution should be exercised when **Vicef®** is administered to a nursing woman. **Vicef® should be given only with special caution to patients with type I or immediate hypersensitivity reactions to penicillin.**

#### Drug Interactions

The concomitant **Vicef®** administration with aminoglycosides or vancomycin or «loop» diuretics increases risk of their nephrotoxicity.

### ADVERSE REACTIONS

**Vicef®** 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

**Vicef®** is administered intravenously (by slow bolus injection of 5 minutes or by infusion of 20-60 minutes) or intramuscularly.

**Adults:** The adult dosage range for ceftazidime is 1 to 6 g per day 8 or 12 hourly (IM or IV). In the majority of infections, 1 g every 8 hours or 2 g every 12 hours should be given. In urinary tract infections and in many less serious infections, 500mg or 1g every 12 hours is usually adequate. In very severe infections, especially immunocompromised patients, including those with neutropenia, 2 g every 8 or 12 hours or 3 g every 12 hours should be administered IV.

**Infants and children:** The usual dosage range for children aged over one month is 30 to 100mg/kg/day, given as two or three divided doses. Doses up to 150mg/kg/day (maximum 6 g daily) in three divided doses may be given IV to infected immunocompromised or fibrocystic children or children with meningitis. *In premature children younger than 1 week old*, the daily dose of 60 mg/kg is divided into 2 IV injections. *In newborns 0-1 week old, with body weight >2000 and newborn 1-4 week old*, the daily dose of 90 mg/kg is divided into 3 IV injections.

*In cystic fibrosis patients*, usual daily dose of ceftazidime is 100-150 mg/kg of body weight, divided into three injections. In adults with severe pseudomonal lung infection and normal renal function, it could be increased till 9 g/day (200 mg/kg).

**Elderly:** In view of the reduced clearance of ceftazidime in acutely ill elderly patients, the daily dosage should not normally exceed 3 g, especially in those over 80 years of age.

*In patients with impaired renal function*, the dosage of **Vicef®** should be reduced. An initial loading dose of 1g of **Vicef®** may be given.

### DOSAGES IN PATIENTS WITH RENAL IMPAIRMENT

Cl <sub>creat</sub> >50 mL/min	Cl <sub>creat</sub> 10-50 mL/min	Cl <sub>creat</sub> <10 mL/min
1-2gm q8h	0.5-1gm q12-24h	0.25-0.5gm q24-48h
Hemodialysis: 50% of dose for normal renal function every 24 hours or 100% of dose for normal renal function every 48 hours; extra 0,5 gm after dialysis.		

### HOW SUPPLIED

**Vicef®** is available in sterile dry powder form in vials containing sterile ceftazidime pentahydrate equivalent to 500 mg or 1,000 mg of ceftazidime for intramuscular and intravenous administration (package of 50 vials).

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

**Vicef®** is manufactured by ABOLmed Ltd., Russia