Tazimax®

Ceftazidime for Injection

DESCRIPTION

Tazimax® is a preparation of sterile Ceftazidime Pentahydrate a semisynthetic, broad-spectrum, beta-lactam antibiotic for parenteral administration. It is the pentahydrate of pyridinium. Ceftazidime is bactericidal in action, exerting its effect by inhibition of enzymes responsible for cell-wall synthesis. A wide range of gram-negative organisms is susceptible to ceftazidime in vitro, including strains resistant to gentamicin and other aminoglycosides. In addition, ceftazidime has been shown to be active against gram-positive organisms. It is highly stable to most clinically important beta-lactamases, plasmid or chromosomal, which are produced by both gram-negative and gram-positive organisms and, consequently, is active against many strains resistant to ampicillin and other cephalosporins.

INDICATIONS

- Lower Respiratory Tract Infection including pneumonia, caused by *Pseudomonas aeruginosa* and other *Pseudomonas* spp.; *Haemophilus influenzae,* including ampicillin-resistant strains; *Klebsiella* spp.; *Enterobacter* spp.; *Proteus mirabilis; Escherichia coli; Serratia* spp.; *Citrobacter* spp.; *Streptococcus pneumoniae;* and *Staphylococcus aureus* (methicillin-susceptible strains).

- Skin and Skin-Structure Infections caused by *Pseudomonas aeruginosa; Klebsiella* spp.; *Escherichia coli; Proteus* spp., including *Proteus mirabilis* and indole-positive *Proteus; Enterobacter* spp.; *Serratia* spp.; *Staphylococcus aureus* (methicillin-susceptible strains); and *Streptococcus pyogenes* (group A beta-hemolytic streptococci).

- Urinary Tract Infections both complicated and uncomplicated, caused by *Pseudomonas aeruginosa; Enterobacter* spp.; *Proteus* spp., including *Proteus mirabilis* and indole-positive *Proteus; Klebsiella* spp.; and *Escherichia coli.*

- Bacterial Septicemia caused by *Pseudomonas aeruginosa, Klebsiella* spp., *Haemophilus influenzae, Escherichia coli, Serratia* spp., *Streptococcus pneumoniae,* and *Staphylococcus aureus* (methicillin-susceptible strains).

- Bone and Joint Infections caused by *Pseudomonas aeruginosa, Klebsiella* spp., *Enterobacter* spp., and *Staphylococcus aureus* (methicillin-susceptible strains).

- Gynecologic Infections including endometritis, pelvic cellulitis, and other infections of the female genital tract caused by *Escherichia coli.*

- Intra-abdominal Infections including peritonitis caused by *Escherichia coli, Klebsiella* spp., and *Staphylococcus aureus* (methicillin-susceptible strains) and polymicrobial infections caused by aerobic and anaerobic organisms and *Bacteroides* spp. (many strains of Bacteroides fragilis are resistant).

- Central Nervous System Infections including meningitis, caused by *Haemophilus influenzae* and *Neisseria meningitidis.* Ceftazidime has also been used successfully in a limited number of cases of meningitis due to *Pseudomonas aeruginosa* and *Streptococcus pneumoniae.*

DOSAGE AND ADMINISTRATION

Adults:

Indication	Dose	Frequency
Usual recommended dosage	1 g IV or IM	8-12 hourly
Uncomplicated urinary tract infections	250 mg IV or IM	12 hourly
Bone and joint infections	2 g IV	12 hourly
Complicated urinary tract infections	500 mg IV or IM	8-12 hourly
Uncomplicated pneumonia; mild skin and skin-structure infections	500 mg to 1 g IV or IM	8 hourly
Serious gynecologic and intra-abdominal infections	2 g IV	8 hourly
Meningitis	2 g IV	8 hourly
Very severe life-threatening infections, especially in immunocompromised patients	2 g IV	8 hourly
Lung infections caused by *Pseudomonas* spp. in patients with cystic fibrosis with normal renal function	30-50 mg/kg IV to a maximum of 6 g per day	8 hourly

- **Neonates (0-4 weeks):** 30 mg/kg IV 12 hourly.

- **Infants and children (1 month-12 years):** 30-50 mg/kg IV to a maximum of 6 grams per day 8 hourly.

- **Impaired Hepatic Function:** No adjustment in dosage is required for patients with hepatic dysfunction.

- **Impaired Renal Function:** Ceftazidime is excreted by the kidneys, almost exclusively by glomerular filtration. Therefore, in patients with impaired renal function (glomerular filtration rate [GFR] <50 mL/min), it is recommended that the dosage of ceftazidime be reduced to compensate for its slower excretion.

INSTRUCTIONS FOR CONSTITUTION

Dose	Route of Administration	Amount of Diluent to be added (mL)
250 mg	IM	1 mL
	IV	2.5 mL
1 g	IM	3 mL
	IV	10 mL

- Insert the syringe needle through the vial closure and inject the recommended volume of diluents. The vacuum may assist entry of the diluent. Remove the syringe needle.

- Shake to dissolve; a clear solution will be obtained in 1 to 2 minutes.

- Invert the vial. Ensuring that the syringe plunger is fully depressed, insert the needle through the vial closure and withdraw the total volume of solution into the syringe (the pressure in the vial may aid withdrawal). Ensure that the needle remains within the solution and does not enter the headspace. The withdrawn solution may contain some bubbles of carbon dioxide.

Note: As with the administration of all parenteral products, accumulated gases should be expressed from the syringe immediately before injection of ceftazidime.

CONTRAINDICATIONS

It is contraindicated in patients who have shown hypersensitivity to ceftazidime or the cephalosporin group of antibiotics.

PRECAUTIONS

High and prolonged serum ceftazidime concentrations can occur from usual dosages in patients with transient or persistent reduction of urinary output because of renal insufficiency. The total daily dosage should be reduced when ceftazidime is administered to patients with renal insufficiency. *Clostridium difficile* associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including ceftazidime, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile.*

SIDE-EFFECTS

● Nausea, vomiting ● Headache, dizziness

PREGNANCY AND LACTATION

Pregnancy Category B. There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed. Ceftazidime is excreted in human milk in low concentrations. Caution should be exercised when ceftazidime is administered to a nursing woman.

PHARMACEUTICAL PRECAUTION

Do not store above 25 °C temperature. Keep away from light and wet place. Keep out of reach of children.
Reconstituted solution is stable for 12 hours at controlled room temperature (20-25 °C) and for 3 days in a refrigerator (2-8 °C temperature).

PACKAGING

Tazimax® 250 IM/IV Injection: Box containing one vial of sterile mixture of Ceftazidime Pentahydrate USP and Sodium Carbonate equivalent to Ceftazidime 250 mg and one ampoule of 5 mL sterile water for injection USP as solvent.

Tazimax® 1g IM/IV Injection: Box containing one vial of sterile mixture of Ceftazidime Pentahydrate USP and Sodium Carbonate equivalent to Ceftazidime 1 g and one ampoule of 10 mL sterile water for injection USP as solvent.

SK+F
Manufactured by
ESKAYEF PHARMACEUTICALS LTD.
TONGI, GAZIPUR, BANGLADESH
® REGD. TRADEMARK

PM02812 V02