Maxidim®

Ceftazidime
IV/IM Injection

Description

Maxidim® (Ceftazidime) is a semisynthetic, broad-spectrum, beta-lactam antibiotic for parenteral administration. 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 and Uses

Maxidim® Injection is indicated for the treatment of patients with infections caused by susceptible strains of the designated organisms in the following diseases:

Lower Respiratory Tract Infections, 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.

Central Nervous System Infections, including meningitis, caused by *Haemophilus influenzae* and *Neisseria meningitidis, Pseudomonas aeruginosa* and *Streptococcus pneumoniae.*

Contraindications

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

Dosage

The usual adult dosage is 1 gram administered intravenously or intramuscularly every 8 to 12 hours. The dosage and route should be determined by the susceptibility of the causative organisms, the severity of infection and the condition, and renal function of the patient.

Recommended Dosage Schedule

	Dose	Frequency
Adults		
Usual recommended dosage	**1 gram IV or IM**	**q8-12hr**
Uncomplicated urinary tract infections	250 mg IV or IM	q12hr
Bone and joint infections	2 grams IV	q12hr
Complicated urinary tract infections	500 mg IV or IM	q8-12hr
Uncomplicated pneumonia; mild skin and skin structure infections	500 mg-1 gram IV or IM	q8hr
Serious gynecologic and intra-abdominal infections	2 grams IV	q8hr
Meningitis	2 grams IV	q8hr
Very severe life-threatening infections, especially in immunocompromised patients	2 grams IV	q8hr
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 grams per day	q8hr
Neonates (0-4 weeks)	30 mg/kg IV	q12hr
Infants and children (1 month-12 years)	30-50 mg/kg IV to a maximum of 6 grams per day†	q8hr

* Although clinical improvement has been shown, bacteriologic cures cannot be expected in patients with chronic respiratory disease and cystic fibrosis.

† The higher dose should be reserved for immunocompromised pediatric patients or pediatric patients with cystic fibrosis or meningitis.

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. In patients with suspected renal insufficiency, an initial loading dose of 1 gram of Ceftazidime may be given. An estimate of GFR should be made to determine the appropriate maintenance dosage.

Administration: Maxidim® may be given intravenously or by deep IM injection into a large muscle mass such as the upper outer quadrant of the gluteus maximus or lateral proof of the thigh. Intra-arterial administration should be avoided. For IV/IM administration, Maxidim® should be reconstituted with the supplied Sterile Water for Injection.

Direction for Reconstitution:

Single-dose vial Administration Amount of WFI to be added: 250 mg IM in 1.5 ml, 250 mg IV in 5 ml, 500 mg IM in 1.5 ml, 500 mg IV in 5 ml and 1 g IM in 3 ml, 1 g IV in 10 ml.

Precautions

The total daily dosage should be reduced when Ceftazidime is administered to patients with renal insufficiency. Ceftazidime should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Side Effects

The most common side-effects are local reactions following IV injection and allergic and gastrointestinal reactions. Hypersensitivity reactions are pruritus, rash, and fever. Angioedema and anaphylaxis have been reported very rarely. Gastrointestinal symptoms are diarrhea, nausea, vomiting, and abdominal pain. Central nervous system reactions included headache, dizziness, and paresthesia.

Use in Pregnancy & Lactation

Pregnancy: No adequate and well controlled studies in pregnant women have been conducted with Ceftazidime. Because animal reproduction studies are not always predictive of human response this drug should be used during pregnancy only if clearly needed.

Lactation: Ceftazidime is excreted in human milk in low concentrations. Because many drugs are excreted in human milk and because safety of the component of the injections in nursing infants has not been established, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Overdosage

Ceftazidime overdosage has occurred in patients with renal failure. Reactions have included seizure activity, encephalopathy, asterixis, neuromuscular excitability, and coma. Patients who receive an acute overdosage should be carefully observed and given supportive treatment.

Commercial Pack

Maxidim® 250 mg IV/IM Injection: Pack of 1 vial containing Sterile mixture of Ceftazidime Pentahydrate and Sodium Carbonate USP equivalent to Ceftazidime 250 mg accompained by an ampoule of 5 ml Water for Injection BP, a 5 ml disposable syringe, a first aid band & an alcohol pad.

Maxidim® 500 mg IV/IM Injection: Pack of 1 vial containing Sterile mixture of Ceftazidime Pentahydrate and Sodium Carbonate USP equivalent to Ceftazidime 500 mg accompained by an ampoule of 5 ml Water for Injection BP, a 5 ml disposable syringe, a first aid band & an alcohol pad.

Maxidim® 1 g IV/IM Injection: Pack of 1 vial containing Sterile mixture of Ceftazidime Pentahydrate and Sodium Carbonate USP equivalent to Ceftazidime 1 g accompained by an ampoule of 5 ml Water for Injection BP, a 5 ml disposable syringe, a first aid band & an alcohol pad.

BEXIMCO PHARMA

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