Cefipime®
(Cefepime USP)

سیفی پائم
۵۰۰ ملی گرام، ۱۰۰۰ ملی گرام
آئی وی۔ آئی ایم انجیکشن

Injection
500mg & 1000mg IV/IM Injection

COMPOSITION:
Cefipime 500 mg IV / IM injection: Each vial contains Cefepime* L-arginine sterile USP equivalent to Cefepime 500 mg. (* as Cefepime HCl)

Cefipime 1000 mg IV / IM injection: Each vial contains Cefepime* L-arginine sterile USP equivalent to Cefepime 1000 mg. (* as Cefepime HCl)

DESCRIPTION:
Cefepime is a fourth generation cephalosporin antibiotic for parenteral use. As a beta-lactam antibiotic, it acts bactericidally by preventing cell-wall synthesis in bacteria. Cefepime, is effective against numerous clinically significant Gram-positive and Gram-negative bacteria, including both aerobes and anaerobes. It is stable against the action of most beta-lactamases.

INDICATIONS
Cefepime is indicated in the treatment of the following infections caused by susceptible strains of the designated microorganisms:

Pneumonia (moderate to severe) caused by Streptococcus pneumoniae, including cases associated with concurrent bacteremia, *Pseudomonas aeruginosa, Klebsiella pneumoniae,* or *Enterobacter species.*

Empiric Therapy for Febrile Neutropenic Patients. Cefepime as monotherapy is indicated for empiric treatment of febrile neutropenic patients. In patients at high risk for severe infection (including patients with a history of recent bone marrow transplantation, with hypotension at presentation, with an underlying hematologic malignancy, or with severe or prolonged neutropenia), antimicrobial monotherapy may not be appropriate.

Uncomplicated and Complicated Urinary Tract Infections (including pyelonephritis) caused by *Escherichia coli* or *Klebsiella pneumoniae,* when the infection is severe, or caused by *Escherichia coli, Klebsiella pneumoniae,* or *Proteus mirabilis,* when the infection is mild to moderate, including cases associated with concurrent bacteremia with these microorganisms.

Uncomplicated Skin and Skin Structure Infections caused by *Staphylococcus aureus* (methicillin-susceptible strains only) or *Streptococcus pyogenes*.

Complicated Intra-abdominal Infections (used in combination with metronidazole) caused by *Escherichia coli*, viridans group *streptococci, Pseudomonas aeruginosa, Klebsiella pneumoniae, Enterobacter species,* or *Bacteroides fragilis.*

Culture and susceptibility testing should be performed where appropriate to determine the susceptibility of the causative microorganism(s) to Cefepime.

Therapy with Cefepime may be instituted before results of susceptibility testing are known; however, once these results become available, the antibiotic treatment should be adjusted accordingly.

Pediatrics
The safety and effectiveness of Cefepime in the following Indications have been established:

Uncomplicated and complicated urinary tract infections (including pyelonephritis), uncomplicated skin and skin structure infections, pneumonia, and as empiric therapy for febrile neutropenic patients in the age groups 2 months up to 16 years. Use of Cefepime in these age groups is supported by evidence from adequate and well controlled studies of Cefepime in adults with additional pharmacokinetic and safety data from pediatric trials.

Safety and effectiveness in pediatric patients below the age of 2 months have not been established.

DOSAGE
The recommended adult and pediatric dosages and routes of administration are:

outlines in the following table. Cefepime should be administered intravenously over approximately 30 minutes.

Recommended Dosage Schedule of **Cefepime with CrCL>60mL/min**			
Site and type of infection	**Dosage**	**Frequency**	**Duration (days)**
Moderate to Severe Pneumonia due to *S.pneumoniae* *, *P. aeruginosa, K. pneumoniae,* or *Enterobacter species.*	1-2 g IV	q12h	10
Empiric therapy for febrile neutropenic patients	2 g IV	q8h	7**
Mild to Moderate Uncomplicated or Complecated Urinary Tract Infections, including pyelonephritis due to *E. coli or K.pneumoniae**	0.5-1 g IV/IM***	q12h	7-10
Serve Uncomplicated or Complecated Urinary Tract Infections, including pyelonephritis due to *E. coli or K.pneumoniae**	2 g IV	q12h	10
Moderate to Serve Uncomplicated Skin and Skin Structure Infections due to *S. aureus or S. Pyogenes.*	2 g IV	q12h	10
Complicated Intra-abdominal Infections (Used in combination with metronidazole) caused by E. coli, viridans group *streptococci, P. aeruginosa, K. pneumoniae, Enterobacter species,* or *B. fragilis.*	2 g IV	q12h	7-10
Pediatric patients (2 monts up to 16 years)	The maximum dose for pediatric patients should not exceed the recommended dose the usual recommended dosage in pediatric patients up to 40 kg in weight for uncomplecated and complicated urinary tract infections (including pyelonephritis), uncomplicated skin and skin structure infections, and pneumonia is 50mg/kg/dose, administered g12h. (50 mg/kg/dose, q8h for febrile neutropenic patients), for durations as given above.		

Recommended Dosing Schedule for **Cefepime in Adult Patients (Normal Renal Function, Renal Insufficiency, and Hemodialysis)**

Creatinine Clearance (mL/min)	**Recommended Maintenance Dosage Schedule**			
> 60 Normal Recommended dosing schedule	500 mg q12h	1 g q12h	2 g q12h	2 g q8h
30-60	500 mg q24h	1 g q24h	2 g q24h	2 g q12h
11-29	500 mg q24h	500 g q24h	1 g q24h	2 g q24h
<11	250 mg q24h	250 mg q24h	500 mg q24h	1 g q24h
CAPD	500 mg q48h	1 g q48h	2 g q48h	2 g q48h
Hemodialysis	1 g on day 1, 500 mg q24h thereafter			2 g q48h
* on hemodialysis days, Cefepime should be administered following hemodialysis. Whenever possible, Cefepime should be administered at the same time each day.				

ADMINISTRATION
Cefepime power is to be constituted using the volumes of diluent as shown in the following table:

Preprations of Solutions of Cefepime

Route of administration	**Dosage**	**Vol. of diluent to be added**
IV	500mg vial 1g vial	5ml 10ml
IM	500mg vial 1g vial	1.5ml 3.0ml

Intramuscularly: Deep intermuscular injection into a large muscle mass (e.g. upper outer quadrant of gluteus maximus)

Intravenously: Preferable route for patients with severe or life-threatening infections perticularly if the possibility of shock is present.

CONTRAINDICATIONS
Cefepime is contraindicated in patients who have had previous hypersensitivity reactions to any component of the formulation, the cephalosporin class of antibiotics, penicillins or other beta-lactam antibiotics.

PRECAUTIONS
Use carefully in patients with know allergies, especially to drugs. As with other antibiotics Cefepime treatment may result in overgrowth of non-susceptible organisms and thus result in super-infection. Some patients report - Pseudomembranous colitis.

Care should be taken in patients with impaired renal function. Renal function should be monitored carefully if drugs with nephrotoxic potential, such as aminoglycosides and potent diuretics are administered with Cefepime.

Pregnancy: Reproductive studies in mice, rats, and rabbits showed no evidence of fetal damage; however; there are no adequate and well-controlled studies in pregnant women thus drug should be used during pregnancy only if clearly needed.

Nursing Mothers: Cefepime is excreted in human breast milk in very low concentrations. Caution should be used when Cefepime is administered to a nursing woman.

SIDE EFFECTS:
Cefepime is generally well tolerated. The following adverse events were thought to be probably related with Cefepime during evaluation of the drug in clinical trials (n=3125).

INCIDENCE EQUAL TO OR GREATER THAN 1% local reaction (3.0 %), pain and/or inflammation (0.6%); rash (1.1%)

INCIDENCE LESS THAN 1% BUT GREATER THAN 0.1%: colitis including Pseudomembranous colitis). diarrhea, fever, headache, nausea, oral moniliasis, pruritus, urticaria, vaginitis, vomiting.

As with some other drugs in this class, encephalopathy (disturbance of consciousness including confusion, hallucinations, stupor, and coma), mycolonus and seziures have been reported. Although most cases occurred in patients with renal impairment who received doses of Cefepime that exceeded recommended dosage schedules, some cases of encephalopathy occured in patients receiving a dosage adjustment of their renal function. If seizures associated with drug therapy occur, the drugs should discontinued. As with other cephalosporins, anaphylaxis including anaphylactic shock, transient, leukopenia, agranuloctosis and thrombocytopenia have been reported.

PRESENTATION
Cefipime IV/IM Injection 500mg, pack of 1 vial with 1 ampoule of 5 ml water for injection

Cefipime IV/IM injection 1000mg, pack of 1 vial with 1 ampoule of 10 ml water for injection

PHARMACEUTICAL PRECAUTIONS & WARNINGS

Store below 30 C.
Protect from light and moisture.
Use only on medical advice.
Keep out of reach of children.
For IV/IM injection use only.

دوا کو روشنی اور نمی سے محفوظ ۳۰ ڈگری سینٹی گریڈ
سے کم درجہ حرارت پر رکھیں۔
دوا ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
دوا بچوں کی پہنچ سے دور رکھیں۔
صرف آئی وی۔ آئی ایم انجیکشن کے لئے استعمال کریں۔