For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Abridged Prescribing Information
Cefepime and Tazobactam for Injection
Augeoz ®

COMPOSITION:
Each vial contains: Cefepime HCl IP equivalent to Cefepime 1000mg, Tazobactam Sodium equivalent to Tazobactam 125mg

THERAPEUTIC INDICATIONS
Augeoz is used parenterally (IV or IM) for the treatment of moderate-to-severe infections caused by or suspected of being caused by susceptible BL-producing bacteria when cefepime alone would be ineffective : Uncomplicated /complicated urinary tract infections (UTI), uncomplicated skin and skin structure infections and complicated intra-abdominal infections, lower respiratory tract infection including pneumonia and bronchitis, septicaemia, empiric treatment in febrile neutropenic patients.

DOSAGE AND ADMINISTRATION: Adults: Recommended dosage schedule for cefepime and tazobactam for injection in patients with CrCl (creatinine clearance) >60ml/min (expressed as cefepime)

Site and type of infection in adults	Dose	Frequency	Duration (days)
Moderate to severe pneumonia	1-2 g I.V.	12-hourly	10
Empiric treatment in febrile neutropenic patients	2 g I.V.	8-hourly	7
Mild-to-moderate uncomplicated or complicated urinary tract infections	0.5–1g I.V./I.M.**	12-hourly	7–10
Severe uncomplicated or complicated urinary tract infections	2 g I.V.	12-hourly	10
Moderate-to-severe skin and skin structure infections	2 g I.V.	12-hourly	10
Complicated Intra-abdominal infections	2 g I.V.	12-hourly	7–10
**IM route of administration is indicated only for mild to moderate uncomplicated or complicated UTIs due to E.coli, when the IM route is considered to be a more appropriate route of drug administration.			

Maximum adult dose of cefepime should not exceed 6g a day. Paediatric : The usual recommended dosage in pediatric patients up to 40kg in weight for uncomplicated and complicated urinary tract infections (including pyelonephritis), uncomplicated skin and skin structure infections, and pneumonia is 50mg per kg per dose, administered every 12 hours (50 mg per kg per dose, every 8 hours for febrile neutropenic patients), for durations as above. Hepatic Impairment : No adjustment is necessary. Renal Impairment: For dosing in renal impairment and for more details please refer to full prescribing information.

SAFETY-RELATED INFORMATION

Contraindications: Contraindicated in patients who are hypersensitive to the drugs or other cephalosporins and should be used with caution in patients with a history of hypersensitivity to penicillins. Use of cephalosporins should be avoided in patients who have had an immediate-type (anaphylactic) hypersensitivity reaction to penicillins or other beta lactam antibiotics.

Warnings and Precautions: Before therapy with cefepime and tazobactam for infection is instituted, careful inquiry should be made to determine whether the patient has had previous immediate hypersensitivity reaction to cefepime, cephalosporins, penicillins or other drugs. During postmarketing surveillance, serious adverse events have been reported including life-threatening or fatal occurrences of the following: encephalopathy (disturbance of consciousness including confusion, hallucinations, stupor, and coma), myoclonus, and seizures. Most cases occurred in patients with renal impairment. In majority of cases, neurotoxicity were reversible and resolved after discontinuation and /or hemodialysis. Clostridium difficile associated diarrhoea (CDAD) has been reported, and may range in severity from mild diarrhoea to fatal colitis. Careful medical history is necessary. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against C. difficile may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated. Dose adjustment is required with impaired renal function. Monitor renal function if high doses of aminoglycosides are administered concomitantly. Cefepime may be associated with fall in prothrombin activity. Positive direct Coomb's tests have been reported. Prescribe with caution in patients with history of GI disease, particularly colitis. Arginine has been shown to alter glucose metabolism and elevate serum potassium transiently.

Pregnancy and Lactation: Should be used during pregnancy only when clearly indicated. Cefepime is excreted in human breast milk in very low concentration following parenteral administration and the drug should be used with caution in nursing mothers

Adverse Reactions: Adverse events reported with cefepime: *Incidence equal to or greater than 1%:* local reactions including phlebitis, pain and/or inflammation, rash. At the higher dose of 2g q8h, the incidence of probably-related adverse events was higher. They consisted of rash, diarrhoea, nausea, vomiting, pruritus, fever and headache. Adverse laboratory changes reported*: Incidence equal to or greater than 1%:* Positive Coombs test (without haemolysis), decreased phosphorus, increased ALT/SGPT, AST/SGOT, eosinophils, abnormal PTT, PT.

For full prescribing information, please contact Sanofi India Ltd, Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072

Source: Forpar XP Injection (Cipla) dated January 2016; Maxipime (Cefepime Hydrochloride USP) for Injection March 2009
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