

PRESCRIBING INFORMATION

XIDIM® Injection IM/IV
(Ceftazidime for Injection USP)

فِڈِم انجکشن آئی ایم / آئی وی

COMPOSITION:

Xidim injection 500mg

Each vial contains:
Ceftazidime USP.....500mg
(as ceftazidime pentahydrate)

Xidim injection 1g

Each vial contains:
Ceftazidime USP.....1g
(as Ceftazidime pentahydrate)

DESCRIPTION

XIDIM injection is supplied as a white to faintly yellow powder in vial containing Ceftazidime (as pentahydrate) with sodium carbonate (118mg per gram of Ceftazidime). On the addition of water for injection XIDIM injection dissolves with effervescence to produce a solution for injection. XIDIM injection contains approximately 52mg (2.3mEq) of sodium per gram of ceftazidime. 116mg Ceftazidime pentahydrate is equivalent to 100mg ceftazidime free acid.

INDICATIONS

Treatment of single or multiple infections caused by susceptible organisms. May be used alone as first choice drug before the results of sensitivity tests are available. May be used in combination with an aminoglycoside or most other betalactam antibiotics. May be used with an antibiotic against anaerobes when the presence of *Bacteroides fragilis* is suspected.

INDICATION INCLUDE

Severe infections e. g. Septicaemia, bacteraemia, peritonitis, meningitis
Infections in immunosuppressed patients
Infections in patients in intensive care, e.g. infection burns.

Respiratory tract infections including lung infections in cystic fibrosis.

Ear, nose and throat infections

Urinary tract infections

Gastrointestinal, biliary and abdominal infections

Bone and joint infections

Infections associated with haemo and peritoneal dialysis and with continuous ambulatory peritoneal dialysis (CAPD).

Prophylaxis: prostatic surgery (transurethral resection)

DOSAGE

Dosage depends upon the severity, sensitivity, site and type of infections and upon the age and renal function of the patient.

Adults: 1 - 6g/day in 2 or 3 divided doses by IV or IM injection.

Urinary tract and less severe infections - 500mg or 1 g every 12 hours

Most infections

Very severe infections particularly - 1g every 8 hours or 2g every 12 hours

In immunocompromised patients

Including those with neutropenia - 2g every 8 or 12 hours

Fibrocystic adults with - 100-150mg/kg/day in

Pseudomonal lung infections 3 divided doses

When used as a prophylactic agent in prostatic surgery 1g should be given at the injection of anaesthesia. A second dose should be considered at the time of catheter removal. In adults with normal renal function (9g/day has been used without ill effect. Infants and children (> 2 months): 30-100mg per kg per day in 2 or 3 divided doses, doses up to 150mg per day maximum 6g/day) in three divided doses may be given to infected immunocompromised or fibrocystic children or children with meningitis. Neonates (0-2 month): 25-60mg/kg/day in 2 divided doses. In neonates the serum half life of ceftazidime can be 3-4 times that in adults. Use in the elderly in view of the reduced clearance of ceftazidime in acutely ill elderly patients, the daily dosage should not normally exceed 3g especially in those over 80 years of age.

CONTRA-INDICATIONS

Patients with known hypersensitivity to cephalosporin antibiotics.

WARNINGS

Before beginning treatment establish whether the patient has a history of hypersensitivity reactions to ceftazidime, cephalosporins, penicillins or other drugs.

Special caution is necessary when giving ceftazidime to patients who have previously shown type 1 or immediate hypersensitivity reaction to penicillin.

If an allergic reaction to ceftazidime occurs discontinue the drug. Serious hypersensitivity reactions may require epinephrine (adrenaline), hydrocortisone, antihistamine or other emergency measures.

SIDE – EFFECTS

Ceftazidime is generally well tolerated. Adverse reactions are infrequent and include:

Local: phlebitis or thrombophlebitis with IV administration, pain and/or inflammation after IM injection.

Hypersensitivity: maculopapular or urticarial rash, fever, pruritus and very rarely angioedema and anaphylaxis (including bronchospasm and/or hypotension)

As with other cephalosporins. There have been rare reports of toxic epidermal necrolysis.

Gastrointestinal: diarrhea, nausea, vomiting, abdominal pain and very rarely oral thrush or colitis

Genito-urinary: candidiasis, vaginitis

Central nervous system: headache, dizziness, paraesthesia and bad taste. There have reports of neurological sequelae including tremor, Myoclonia, convulsions, and encephalopathy in patients with renal impairment in whom the dose of ceftazidime has not been appropriately reduced.

Laboratory test changes: transient changes note during ceftazidime therapy include: eosinophilia, positive coomb's test, very rarely haemolytic anaemia, thrombocytosis and elevations in one or more of the hepatic enzymes, ALT (SGPT-), AST (SGOT), LDH, GGT and alkaline phosphatase. As with some other cephalosporins, transient elevations of blood urea, blood urea nitrogen and/or serum creatinine have been observed occasionally. Very rarely leucopenia, neutropenia, agranulocytosis, thrombocytopenia and lymphocytosis have been reported.

OVERDOSAGE

Overdosage can lead to neurological sequelae including encephalopathy, convulsions and coma. Serum levels of ceftazidime can be reduced by haemodialysis or peritoneal dialysis.

PRESENTATION

Xidim 500mg vial:

With one 5 ml ampoule of sterile water for injection in a carton

Xidim 1g vial:

With one 10 ml ampoule of sterile water for injection in a carton

STORAGE:

Store at temperature 15 to 30 °C away from light and moisture.

خوراک اور طریقہ استعمال:

خوراک کا دارو مدار: انفیکشن کی شدت، متاثرہ جگہ، انفیکشن کی قسم، مریض کی عمر اور اسکے گردوں کی کارکردگی پر منحصر ہے۔

بالغ: 1 سے 6 گرام روزانہ 2 سے 3 تقسیم شدہ خوراک کے طور پر بذریعہ عضلاتی و ریوی دی جاسکتی ہے۔

یو بی بی ٹی ٹرکیٹ اور کم شدت کے انفیکشن:

500 ملی گرام یا 1 گرام ہر بار دہ گھنٹے کے وقفے سے۔

شدید انفیکشن بطور خاص کم قوت مدافعی والے مریض بشمول ان مریضوں کو جو نیوٹروفیلینیا کے شکار ہوں: 1 گرام

ہر 8 گھنٹے یا 2 گرام ہر بار دہ گھنٹے کے وقفے سے۔

بالغ فیئر ویسک جو Pseudomonal lung انفیکشن کے ساتھ ہوں: 100 سے 150 ملی گرام/کلوگرام روزانہ تین

تقسیم شدہ خوراک کے طور پر اسکا استعمال جب حفاظتی اقدام کے طور پر پراسیکک جراثیمی تو ایک گرام بیوشل کے وقت پر دینا ہوگا۔

دوسری خوراک استعمال تکثیر کالے کے وقت پر کرنا چاہیے۔

اسٹوریج:

15 سے 30 ڈگری سینٹی گریڈ دبیہ حرارت پر روشنی اور نمی سے بچا کر رکھیے

brookes

Manufactured by:

Brookes Pharma Private Limited
58 - 59 Sector 15 Korangi Industrial Area
Karachi 74900 Pakistan

206-228

