SCHEDULING STATUS: S4

PROPRIETARY NAME AND DOSAGE FORMS:

CEFTAZIDIME 1 g OETHMAAN(Powder for solution for injection)

COMPOSITION:

CEFTAZIDIME 1 g OETHMAAN 1 vial with 1,29 g of powder contains ceftazidime pentahydrate corresponding to 1,0 g of ceftazidime.
Inactive ingredient: Sodium carbonate
Sugar free

PHARMACOLOGICAL CLASSIFICATION:

A 20.1.1 Broad and medium spectrum antibiotics

PHARMACOLOGICAL ACTION:

Ceftazidime is a bactericidal cephalosporin antibiotic.

Bacteriology:

Ceftazidime is bactericidal in action, exerting its effect on target cell wall proteins and causing inhibition of cell wall synthesis. A wide range of pathogenic strains and isolates associated with hospital acquired infections are susceptible to ceftazidime in vitro, including resistant strains and multi-resistant strains. It is stable to most clinically important beta-lactamases produced by both Gram-negative and Gram-positive organisms including multi-resistant strains. Ceftazidime has high intrinsic activity in vitro and acts with few changes in minimum inhibitory concentration (MIC) at varied inoculum levels. Ceftazidime has been shown to have in vitro activity against the following organisms:

Gram-negative:

Pseudomonas aeruginosa, Pseudomonas spp. (other), *Klebsiella pneumoniae,* Klebsiella spp. (other), *Proteus mirabilis, Proteus vulgaris, Morganella morganii* (formally *Proteus morganii*), *Proteus rettgeri*, Providencia spp., *Escherichia coli*, Enterobacter spp., Citrobacter spp., Serratia spp., Salmonella spp., Shigella spp., *Yersinia enterocolitica, Pasteurella multocida*, Acinetobacter spp., *Neisseria gonorrhoeae, Neisseria meningitides, Haemophilus influenzae* (including ampicillin-resistant strains), *Haemophilus parainfluenzae* (including ampicillin-resistant strains).

Gram-positive:

Micrococcus spp., *Streptococcus pyogenes,* Streptococcus Group B, *Streptococcus pneumoniae, Streptococcus mitis,* Streptococcus spp., excluding *Enterococcus (Streptococcus) faecalis.* Bacteriodes spp., are mostly resistant. Ceftazidime is not active in vitro against methicillin-resistant Staphylococci, Streptococcus *faecalis* and many other Enterococci, *Listeria monocytogenes*, Campylobacter spp., or *Clostridium difficile.*

After 1 g IM injection, ceftazidime serum levels exceed MIC90 for more than 12 hours for Streptococcus Group A and B (except *Strep. faecalis*), *E. coli, Klebsiella* spp., *Proteusmirabilis,* Proteus spp. (indole positive), Serratia spp., Citobacter spp., Salmonella spp., and *Haemophilus influenzae.*
Ceftazidime is not active against the following bacteria:

Methicillin-resistant staphylococci, *Enterococcus (Streptococcus) faecalis, Clostridium difficile, Listeria monocytogenes,* Campylobacter spp.

Pharmacokinetic Properties:

In healthy subjects, the serum half-life of ceftazidime is 1,8 hours (1,5 to 2 hours) and only slightly altered by dosage or route of administration. The half-life is prolonged in patients with impaired renal function. Ceftazidime has a low serum protein binding (10 %).

INDICATIONS:

CEFTAZIDIME 1g OETHMAAN is indicated for the treatment of the following infections when caused by susceptible organisms:

- **Severe infections including: septicaemia, bacteraemia, peritonitis, and in immunocompromised patients,** caused by *Streptococcus pyogenes*, Streptococcus Group B, *Streptococcus pneumoniae, Streptococcus mitis*, Streptococcus spp., *Escherichia coli, Haemophilus influenzae, Klebsiella pneumoniae,* Salmonella spp., Acinetobacter spp., *Yersinia enterocolitica,* or *Pasteurella multocida.*
- **Respiratory tract infections such as pneumonia, bronchopneumonia, and bronchitis including lung infections in patients with cystic fibrosis,** caused by *Streptococcus pneumoniae, Haemophilus influenzae, Klebsiella pneumoniae, Haemophilus parainfluenzae, Escherichia coli, Streptococcus pyogenes, Proteus mirabilis*, Serratia spp., or Enterobacter spp.
- **Ear, nose and throat infections,** caused by *Streptococcus pneumoniae, Haemophilus influenzae, Klebsiella pneumoniae, Haemophilus parainfluenzae, Escherichia coli, Streptococcus pyogenes, Proteus mirabilis*, Serratia spp., or Enterobacter spp.
- **Urinary tract infections,** caused by *Neisseria gonorrhoeae, Escherichia coli, Proteus mirabilis, Klebsiella pneumoniae, Proteus vulgaris, Morganella morganii, Enterobacter spp.,* or *Citrobacter spp.*
- **Skin and soft tissue infections,** caused by Streptococcus pyogenes, Streptococcus spp., Escherichia coli, Enterobacter spp., Klebsiella pneumoniae, Proteus mirabilis, or Morganella morganii.
- **Gastrointestinal, biliary and abdominal infections,** caused by *Escherichia coli, Klebsiella pneumoniae, Streptococcus spp., Salmonella spp., Shigella spp.,* or *Yersinia enterocolitica.*

CONTRAINDICATIONS:

Hypersensitivity to cephalosporin antibiotics.

WARNINGS AND SPECIAL PRECAUTIONS:

Great care should be taken if CEFTAZIDIME 1 g OETHMAAN is to be given to patients who are penicillin-sensitive. Care is also necessary in patients with known histories of allergy.

CEFTAZIDIME 1g OETHMAAN should be given with caution to patients with renal impairment; a dosage reduction is necessary. Renal and haematological status should be monitored especially during prolonged and high-dose therapy.

CEFTAZIDIME 1g OETHMAAN may interfere with the Jaffé method of measuring creatinine concentrations and may produce falsely high values; this should be borne in mind when measuring renal function. Positive results to the direct Coombs' test have been found during treatment with CEFTAZIDIME 1g OETHMAAN and these can interfere with blood cross-matching.
The urine of patients being treated with CEFTAZIDIME 1g OETHMAAN may give false-positive reactions for glucose using copper-reduction reactions.

INTERACTIONS:

The concomitant use of a nephrotoxic medicine such as the aminoglycoside gentamicin may increase the risk of kidney damage with CEFTAZIDIME 1g OETHMAAN.
There is also some evidence for enhanced nephrotoxicity with a loop diuretic like furosemide. The renal excretion of CEFTAZIDIME 1g OETHMAANis inhibited by probenecid.
There may be antagonism between CEFTAZIDIME 1g OETHMAAN and bacteriostatic antibacterials.

HUMAN REPRODUCTION:

The safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

CEFTAZIDIME 1g OETHMAAN is given by deep intramuscular injection, slow intravenous injection over 3 to 5 minutes, or intravenous infusion over up to 30 minutes.

Adults:

The usual dose for adults ranges from 1 to 6 g daily in divided doses every 8 to 12 hours. The higher doses are used in severe infections especially in immunocompromised patients. In adults with cystic fibrosis who have pseudomonal lung infection, high doses of 90 to 150 mg per kg body-weight daily in 3 divided doses are used; up to 9 g daily has been given to adults with normal function. Single doses of more than 1 g should be given intravenously.

Children:

Children are usually given 30 to 100 mg per kg daily in 2 or 3 divided doses, but in severely ill children up to 150 mg per kg daily to a maximum of 6 g daily may be given in 3 divided doses.

Neonates and infants up to 2 months old:

A dose of 25 to 60 mg per kg daily in 2 divided doses is effective.

Elderly:

In the elderly, the dose should generally not exceed 3 g daily.

Renal impairment:

In patients with renal impairment the dosage of CEFTAZIDIME 1g OETHMAAN may need to be reduced. Following a loading dose of 1 g, maintenance doses are based on the creatinine clearance.

Maintenance doses are:

Creatinine clearance (ml/min)	Recommended dosage
31 to 50	1 g every 12 hours
16 to 30	1 g every 24 hours
6 to 15	0,5 g every 24 hours
< 5	0,5 g every 48 hours

In severe infection these doses may need to be increased by 50 %. In these patients ceftazidime trough serum concentrations should not exceed 40 µg/ml. In patients undergoing peritoneal dialysis a loading dose of 1 g may be given followed by 500 mg every 24 hours; ceftazidime sodium may also be added to the dialysis fluid, usually 125 to 250 mg of ceftazidime for 2 litres of dialysis fluid. In patients undergoing haemodialysis a loading dose of 1 g is given and should be repeated after each dialysis period.

Administration:

CEFTAZIDIME 1g OETHMAAN may be given intravenously or by deep intramuscular injection into a large muscle mass such as the upper outer quadrant of the *gluteus maximus* or lateral part of the thigh.

Instructions for reconstitution:

It is preferable to use freshly constituted solutions of CEFTAZIDIME 1g OETHMAAN. See table below for addition volumes and solution concentrations:

Vial size	Amount of diluent to be added (ml)	Approximate concentration (mg/ml)
0,5 g intramuscular	1,5	238
0,5 g intravenous	5,0	91
1 g intramuscular	3,0	263
1 g intravenous	10	91
2 g intravenous bolus	10	174

When ceftazidime is dissolved, carbon dioxide is released and a positive pressure develops. For ease of use, follow the recommended techniques of reconstitution described below.

Intramuscular administration:

Ceftazidime should be reconstituted with Water for Injection or 0,5 % or 1 % Lidocaine hydrochloride injection, as indicated in the table above. The package insert for Lidocaine should be consulted before reconstitution of ceftazidime with lidocaine.

Intravenous administration:

For direct intermittent intravenous administration, reconstitute ceftazidime with Water for Injection (see table above). Slowly inject the solution directly into the vein over a period of up to 5 minutes or give through the tubing of a giving set.

Instructions for reconstitution:

1. Insert the needle through the vial closure and inject the recommended volume of diluent. The vacuum may assist entry of the diluent. Remove the syringe needle.
2. Shake to dissolve; carbon dioxide is released and a clear solution obtained in about 1 to 2 minutes.
3. Invert the vial. With the syringe plunger 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 small bubbles of carbon dioxide, they may be disregarded.

For short intravenous infusion (e.g. up to 30 minutes), CEFTAZIDIME 1g OETHMAAN may be dissolved in 50 ml Water for Injections as follows:

1. Insert the syringe needle through the vial closure and inject 10 ml of diluent. The vacuum may assist entry of the diluent. Remove the syringe needle.
2. Shake to dissolve; carbon dioxide is released and a clear solution obtained in about 1 to 2 minutes.
3. Insert a gas relief needle through the vial closure to relieve the internal pressure. With the gas relief in position, add the remaining 40 ml of diluent. Remove the gas relief needle and syringe needle; shake the vial and set up for infusion use in the normal way.

Note: To preserve product sterility, it is important that a gas relief needle is not inserted through the vial closure before the product has dissolved.

These solutions may be given directly into the vein or introduced into the tubing of a giving set if the patient is receiving parenteral fluids.

Compatibility with fluids:

CEFTAZIDIME 1g OETHMAAN should not be mixed with solutions with a pH above 7,5, for example sodium bicarbonate solution for injection. CEFTAZIDIME 1g OETHMAAN and aminoglycosides should not be mixed in the solution for injection because of the risk for precipitation. At ceftazidime concentrations between 20 mg/ml and 333 mg/ml the CEFTAZIDIME 1g OETHMAAN powders for injection/infusion may be mixed in commonly used solutions for infusion:

- 0,9 % sodium chloride solution (physiological saline solution)
- 5 % glucose solution
- 0,9 % sodium chloride + 5 % glucose solution
- Ringer's Lactate Solution

When reconstituted for intramuscular use, CEFTAZIDIME 1g OETHMAAN powder for injection/infusion can also be diluted with 1 % lidocaine solutions.

SIDE EFFECTS

Haematological disorders:

The following side-effects have been reported and the frequencies are unknown: neutropenia and thrombocytopaenia. Bleeding complications related to hypothrombinaemia and/or platelet dysfunction have occurred. Haemolytic anaemia may also occur.

Gastrointestinal disorders:

The following side-effects have been reported and the frequencies are unknown: gastrointestinal adverse effects such as nausea, vomiting, and diarrhoea. Prolonged use may result in overgrowth of non-susceptible organisms and pseudomembranous colitis may develop.

Hepato-biliary disorders:

The following side-effects have been reported and the frequencies are unknown: transient increases in liver enzyme values. Hepatitis and cholestatic jaundice.

Immune system disorders (including skin reactions):

The following side-effects have been reported and the frequencies are unknown: the most common adverse effects are hypersensitivity reactions, including skin reactions, urticaria, eosinophilia, fever, reactions resembling serum sickness, and anaphylaxis.

Nervous system disorders:

The following side-effects have been reported and the frequencies are unknown: convulsions and other signs of CNS toxicity have been associated with high doses, especially in patients with severe renal impairment.

Renal and urinary disorders:

The following side-effects have been reported and the frequencies are unknown: nephrotoxicity. Acute renal tubular necrosis has followed excessive dosage and has also been associated with its use in older patients or those with pre-existing renal impairment or those with the concomitant administration of nephrotoxic medicines such as aminoglycosides. Acute interstitial nephritis is also a possibility as a manifestation of hypersensitivity.

General disorders and administration site conditions:

The following side-effects have been reported but the frequencies are unknown: there may be pain at the injection site following intra-muscular administration, and thrombophlebitis has occurred following intravenous infusion. There may be a positive response to the Coombs' test.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See "SIDE EFFECTS and WARNINGS AND SPECIAL PRECAUTIONS".
Serum levels of CEFTAZIDIME 1g OETHMAAN are reduced by dialysis. Treatment is supportive and symptomatic.

IDENTIFICATION:

CEFTAZIDIME 1 g OETHMAAN: a white to cream coloured powder.

PRESENTATION:

CEFTAZIDIME 1 g OETHMAAN powder for solution for injection is packed in cartons containing 1 or 10 single dose, clear, colourless glass vial/s with a grey rubber stopper and aluminium cap with a red flip-off seal.

STORAGE INSTRUCTIONS:

Store in the original packaging (in the carton) at or below 25 °C.
The reconstituted solution is intended for immediate use, but the solution may be stored in the original vials in the refrigerator at 2 to 8 °C for 24 hours. After use, discard any remaining solution.
KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBERS:

CEFTAZIDIME 1 g OETHMAAN: 41/20.1.1/0922

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

OETHMAAN BIOSIMS (PTY) LTD.
207A Sherwood House
Greenacres Office Park
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DATE OF PUBLICATION OF THIS PACKAGE INSERT:

08 February 2008

SKEDULERINGSTATUS: S4

HANDELSNAAM EN DOSEERVORM

CEFTAZIDIME 1 g OETHMAAN (poeier vir oplossing vir inspuiting)

SAMESTELLING
CEFTAZIDIME 1 g OETHMAAN 1 flessie met 1,29 g poeier bevat keftasidiempentahidraat gelykstaande aan 1,0 g keftasidiem.
Onaktiewe bestanddeel: Natriumkarbonaat
Suiker vry

FARMAKOLOGIESE KLASSIFIKASIE
A. 20.1.1 Breë- en mediumspektrumantibiotika

FARMAKOLOGIESE WERKING
Keftasidiem is 'n bakteriedodende kefalosporienantibiotikum.

Bakteriologie
Keftasidiem is bakteriedodend van werking en oefen sy effek uit op teikenselwandproteïene en veroorsaak remming van selwandsintese. 'n Wye verskeidenheid van patogene stamme en isolate wat verband hou met hospitaalverworwe infeksies, is in vitro vatbaar vir keftasidiem, waaronder weerstandige stamme en multiweerstandige stamme. Dit is stabiel teen die meeste klinies belangrike beta-laktamases wat deur Gram-negatiewe en Gram-positiewe organismes geproduseer word, waaronder multiweerstandige stamme. Keftasidiem het in vitro 'n hoë intrinsieke aktiwiteit en werk met 'n paar verskille in die minimum inhibisiekonsentrasie (MIK) by verskillende inokulumvlakke. Dit is getoon dat keftasidiem in vitro aktiwiteit teen die volgende organismes het:

Gram-negatief
Pseudomonas aeruginosa, Pseudomonas spp. (ander), *Klebsiella pneumoniae, Klebsiella* spp. (ander), *Proteus mirabilis, Proteus vulgaris, Morganella morganii* (formeel *Proteus morganii*), *Proteus rettgeri, Providencia spp., Escherichia coli, Enterobacter spp., Citrobacter spp., Serratia spp., Salmonella spp., Shigella spp., Yersinia enterocolitica, Pasteurella multocida, Acinetobacter spp., Neisseria gonorrhoeae, Neisseria meningitides, Haemophilus influenzae (insluitend ampisillien-weerstandige stamme), Haemophilus parainfluenzae* (insluitend ampisillien-weerstandige stamme).

Gram-positief
Micrococcus spp., *Streptococcus pyogenes*, Streptococcus Groep B, *Streptococcus pneumoniae, Streptococcus mitis*, Streptococcus spp., uitgesluit *Enterococcus (Streptococcus)* faecalis. Bacteriodes spp., is meestal weerstandig. Keftasidiem is nie in *vitro* aktief teen metisillienweerstandige stafilokokke, *Streptococcus faecalis* en baie ander enterokokke, Listeria monocytogenes, Campylobacter spp., of *Clostridium difficile*.

Na inspuiting van 1 g IM oorskry die serumvlakke van keftasidiem MIC90 vir meer as 12 uur vir Streptococcus Groep A en B (behalwe *Strep. faecalis*), *E. coli*, Klebsiella spp., *Proteusmirabilis*, Proteus spp. (indool positief), Serratia spp., Citrobacter spp., Salmonella spp., en

Haemophilus influenzae.
Keftasidiem is nie aktief teen die volgende bakterieë nie:
Metisillien-weerstandige stafilokokke, *Enterococcus (Streptococcus) faecalis, Clostridium difficile, Listeria monocytogenes*, Campylobacter spp.

Farmakokinetiese eienskappe
In gesonde mense is die serumhalfleeftyd van keftasidiem 1,8 uur (1,5 tot 2 uur) en dit word min deur die dosis of toedieningsroete beïnvloed. Die halfleeftyd is langer in pasiënte met swak lewerfunksie. Keftasidiem het 'n lae serumproteïenbinding (10 %).

INDIKASIES
CEFTAZIDIME 1 g OETHMAAN is aangedui vir die behandeling van die volgende infeksies wanneer deur vatbare organismes veroorsaak:

- **Erge infeksies, waaronder septisemie, bakteremie, peritonitis, en in pasiënte met swak immuunstelsel,** infeksies deur Streptococcus pyogenes, streptokokkus Groep B, *Streptococcus pneumoniae, Streptococcus mitis*, streptokokkus spp., *Escherichia coli, Haemophilus influenzae, Klebsiella pneumoniae,* Salmonella spp., Acinetobacter spp., *Yersinia enterocolitica,* of *Pasteurella multocida.*
- **Respiratoriese infeksies soos longontsteking, brongopneumonie en brongitis, insluitend longinfeksies in pasiënte met sistiese fibrose,** veroorsaak deur *Streptococcus pneumoniae, Haemophilus influenzae, Klebsiella pneumoniae, Haemophilus parainfluenzae, Escherichia coli, Streptococcus pyogenes, Proteus mirabilis,* Serratia spp., of enterobakter spp.
- **Oor-, neus- en keelinfeksies,** veroorsaak deur *Streptococcus pneumoniae, Haemophilus influenzae, Klebsiella pneumoniae, Haemophilus parainfluenzae, Escherichia coli, Streptococcus pyogenes, Proteus mirabilis*, Serratia spp., ff Enterobacter spp.
- **Urienweginfeksies,** veroorsaak deur *Neisseria gonorrhoeae, Escherichia coli, Proteus mirabilis, Klebsiella pneumoniae, Proteus vulgaris, Morganella morganii,* Enterobacter spp., of Citrobacter spp.
- **Vel- en sagteweefselinfeksies,** veroorsaak deur *Streptococcus pyogenes, Streptococcus* spp., *Escherichia coli,* Enterobacter spp., *Klebsiella pneumoniae, Proteus mirabilis, of Morganella morganii.*
- **Gastro-intestinale, gal- en abdominale infeksies,** veroorsaak deur *Escherichia coli, Klebsiella pneumoniae* , Streptococcus spp., Salmonella spp., Shigella spp., of *Yersinia enterocolitica.*

KONTRA-INDIKASIES
Hipersensitiwiteit vir kefalosporienantibiotika.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREëLS
Wees baie versigtig as CEFTAZIDIME 1 g OETHMAAN gegee word aan pasiënte wat penisillien-sensitief is. Wees ook versigtig met pasiënte met 'n bekende geskiedenis van allergie.

CEFTAZIDIME 1 g OETHMAAN moet versigtig gegee word aan pasiënte met swak nierfunksie; 'n verlaging van die dosis is nodig. Nier- en hematologiese status moet veral tydens langdurige behandeling en met hoë dosisse gemonitor word.

CEFTAZIDIME 1 g OETHMAAN kan inmeng met die Jaffé-metode om kreatinienkonsentrasies te meet en kan vals hoë waardes gee; dit moet in gedagte gehou word wanneer die nierfunksie gemeet word. Positiewe resultate vir die direkte Coombs-toets is tydens behandeling met CEFTAZIDIME 1 g OETHMAAN gekry en dit kan inmeng met toetse vir verenigbaarheid van bloed

Die urien van pasiënte wat met CEFTAZIDIME 1 g OETHMAAN behandel word, kan valse positiewe reaksies vir glukose gee as dit die koperreduksiereaksie gebruik.

INTERAKSIES
Die gelyktydige gebruik van nefrotoksiese medisyne soos aminoglikosiede, gentamisien en tobramisien kan die risiko vir nierskade deur CEFTAZIDIME 1 g OETHMAAN verhoog.
Daar is ook bewyse vir erger nefrotoksisiteit met lusdiuretika soos furosemied. Die renale uitskeiding van CEFTAZIDIME 1 g OETHMAAN word deur probenesied gerem.
Daar kan antagonisme wees tussen CEFTAZIDIME 1 g OETHMAAN en bakteriostatiese antibakteriesemiddels.

MENSLIKE VOORTPLANTING
Veiligheid en effektiwiteit tydens swangerskap en borsvoeding is nie bepaal nie

DOSIS EN GEBRUIKSAANWYSINGS
CEFTAZIDIME 1 g OETHMAAN word gegee deur diep intramuskulêre inspuiting, stadige binneaarse inspuiting oor 3 tot 5 minute, of binneaarse infusie oor tot 30 minute.

Volwassenes
Die gewone dosis vir volwassenes wissel van 1 tot 6 g per dag in verdeelde dosisse elke 8 tot 12 uur. Die hoër dosisse word vir ernstige infeksies gebruik, veral vir pasiënte met 'n immuungebrek. In volwassenes met sistiese fibrose wat longinfeksies deur pseudomonas het, word hoë dosisse van 90 tot 150 mg per kg liggaamsmassa daagliks in 3 verdeelde dosisse gebruik; tot 9 g per dag is aan volwassenes met normale funksie gegee. Enkeldosisse van meer as 1 g moet intraveneus gegee word.

Kinders
Kinders kry gewoonlik 30 tot 100 mg per kg daagliks in 2 of 3 verdeelde dosisse, maar in ernstige siek kinders tot 150 mg per kg daagliks tot 'n maksimum van 6 g per dag mag in 3 verdeelde dosisse gegee word.

Neonate en babas tot 2 maande oud
'n Dosis van 25 tot 60 mg per kg daagliks in 2 verdeelde dosisse is effektief.

Bejaardes
Vir bejaardes moet die dosis oor die algemeen nie 3 g oorskry nie.

Swak nierfunksie
Vir pasiënte met swak nierfunksie kan die dosis CEFTAZIDIME 1 g OETHMAAN dalk verlaag word. Na 'n ladingsdosis van 1 g, is die onderhoudsdosisse gebaseer op die kreatinienopruiming.

Onderhoudsdosisse is:

Kreatinienopruiming (ml/min)	Aanbevole dosis
31 tot 50	1 g elke 12 uur
16 tot 30	1 g elke 24 uur
6 tot 15	0,5 g elke 24 uur
< 5	0,5 g elke 48 uur

Vir erge infeksie moet hierdie dosisse met 50 % verhoog word. Vir hierdie pasiënte moet die trogkonsentrasie van keftasidiem in die serum nie 40 μ g / ml oorskry nie. Vir pasiënte wat peritoneale dialise ondergaan, kan 'n ladingsdosis van 1 g gegee word, gevolg deur 500 mg elke 24 uur; natriumkeftasidiem kan ook by die dialisevloeistof gevoeg word, gewoonlik 125 tot 250 mg keftasidiem vir 2 liter dialisevloeistof. Vir pasiënte wat hemodialise ondergaan, word 'n ladingsdosis van 1 g gegee en dit moet dit na elke dialiseperiode herhaal word.

Toediening
CEFTAZIDIME 1 g OETHMAAN kan intraveneus of deur diep intramuskulêre inspuiting in 'n groot spiermassa toegedien word, soos die boonste buitenste kwadrant van die *gluteus maximus* of laterale deel van die dy.

Aanwysings vir aanmaak
Dit is verkieslik om vars aangemaakte oplossings van CEFTAZIDIME 1 g OETHMAAN te gebruik. Kyk in die tabel hier onder vir die volume oplosmiddel om by te voeg en die benaderde konsentrasies van die oplossings:

Flessiegrootte	Volume oplosmiddel om by te voeg (ml)	Benaderde konsentrasie (mg/ml)
0,5 g intramuskulêr	1,5	238
0,5 g intraveneus	5,0	91
1 g intramuskulêr	3,0	263
1 g intraveneus	10	91
2 g intraveneuse bolus	10	174

Wanneer keftasidiem opgelos word, word koolstofdioksied vrygestel en ontstaan 'n positiewe druk. Vir gemak van gebruik, volg die aanbevole tegnieke vir die aanmaak wat hieronder beskryf word.

Intramuskulêre toediening:
keftasidiem moet aangemaak word met water vir inspuiting of 0,5 % of 1% lidokaïen-hidrochloried inspuiting, soos in die tabel hier bo aangedui. Die inligting in die voubiljet van lidokaïen moet geraadpleeg word voor die aanmaak van keftasidiem met lidokaïen.

Intraveneuse toediening:
Vir direkte onderbroke intraveneuse toediening, moet keftasidiem met water vir inspuiting aangemaak word (sien tabel hierbo). Spuit die oplossing stadig in die aar oor 'n tydperk van tot 5 minute of gee deur die buis van die toedieningstel.

Aanwysings vir aanmaak:
1. Steek die naald deur die flessie se prop en spuit die aanbevole volume oplosmiddel in. Die vakuum kan die inlaat van die oplosmiddel help. Verwyder die spuitnaald.
2. Skud om op te los; koolstofdioksied word vrygestel en 'n helder oplossing word binne ongeveer 1 tot 2 minute verkry.
3. Keer die flessie om. Steek die naald met die spuit se suier heeltemal ingedruk deur die flessie se prop, en trek die volle volume oplossing op in die spuit (die druk in die flessie kan die onttrekking aanhelp).Maak seker dat die naald binne die oplossing bly en nie in die kopspasie kom nie. Die onttrekte oplossing kan klein borreltjies koolstofdioksied bevat, en hulle kan geïgnoreer word.

Vir kort intraveneuse infusie (bv. tot 30 minute), kan CEFTAZIDIME 1 g OETHMAAN soos volg in 50 ml water vir inspuiting opgelos word:
1. Steek die spuitnaald deur die flessie se prop en spuit 10 ml oplosmiddel in. Die vakuum kan die inlaat van die oplosmiddel help. Verwyder die spuitnaald.
2. Skud om op te los; koolstofdioksied word vrygestel en 'n helder oplossing word binne ongeveer 1 tot 2 minute verkry.
3. Steek 'n naald in deur die flessie se prop om die interne druk te verlig. Met die gasverligting in posisie, voeg die oorblywende 40 ml verdunningsmiddel by. Verwyder die gasverlignaald en spuitnaald; skud die flessie en stel op die normale manier om infusie te gebruik.

Let wel: Om steriliteit van die produk te bewaar, is dit belangrik dat 'n gasverlignaald nie deur die flessie se prop gesteek word voordat die produk opgelos is nie.

Hierdie oplossings kan direk in die aar ingedien word of in die buis van 'n toedieningstel indien die pasiënt parenterale vloeistowwe ontvang.

Verenigbaarheid met vloeistowwe:
CEFTAZIDIME 1 g OETHMAAN moet nie met oplossings met 'n pH bo 7,5 gemeng word nie, byvoorbeeld natriumbikarbonaatoplossing vir inspuiting. CEFTAZIDIME 1 g OETHMAAN en aminoglikosiede moet as gevolg van die risiko vir neerslag nie in die oplossing vir inspuiting gemeng word nie.
By konsentrasies van keftasidiem tussen 20 mg/ml en 333 mg/ml kan die CEFTAZIDIME 1 g OETHMAAN-poeier vir inspuiting / infusie met die algemeen gebruikte oplossings vir infusie gemeng word:
- 0,9 % natriumchlorieoplossing (fisiologiese soutoplossing)
- 5 % glukose-oplossing
- 0,9 % natriumchloried- + 5 % glukose-oplossing
- Ringer se laktaatoplossing

Wanneer vir intramuskulêre gebruik aangemaak word, kan CEFTAZIDIME 1 g OETHMAAN-poeier vir inspuiting / infusie ook met 1 % lidokaïenoplossing verdun word.

NEWE-EFFEKTE
Hematologiese versteurings:
Die volgende newe-effekte is aangemeld, maar die frekwensies is onbekend: neutropenie en trombositopenie. Bloedingskomplikasies wat met hipotrombinemie en / of bloedplaatjie-disfunksie verband hou, het voorgekom. Hemolitiese anemie kan ook voorkom.

Gastro-intestinale versteurings:
Die volgende newe-effekte is aangemeld en die frekwensies is onbekend: gastro-intestinale newe-effekte soos naarheid, braking en diarree. Langdurige gebruik kan tot 'n oorgroei van nie-gevoelige organismes en pseudomembraankolitis lei.

Hepatobiliêre versteurings:
Die volgende newe-effekte is aangemeld, maar die frekwensies is onbekend: tydelike stygings in die lewerensiemvlakke Hepatitis en cholestatiese geelsug.

Versteurings van immuunstelsel (waaronder velreaksies ingesluit is):
Die volgende newe-effekte is aangemeld, maar die frekwensies is onbekend: die meeste algemene nadelige effekte is hipersensitiwiteitsreaksies, waaronder velreaksies, urtikarie, eosinofilie, koors, reaksies wat soos serumsiekte lyk en anafilakse.

Versteurings van die senustelsel
Die volgende newe-effekte is aangemeld, maar die frekwensies is onbekend: konvulsies en ander tekens van SSS-toksisiteit het met hoë dosisse gepaardgegaan en veral in pasiënte met erge swak nierfunksie.

Versteurings van die niere en urierweg
Die volgende newe-effekte is aangemeld, maar die frekwensies is onbekend: nefrotoksisiteit. Akute renale tubulêre nekrose het na oormatige dosisse voorgekom en is ook verbind met die gebruik daarvan in ouer pasiënte of persone met voorafbestaande swak nierfunksie of diegene met die geïyktydige toediening van nefrotoksiese medisyne soos aminoglikosiede. Akute interstisiële nefritis is ook 'n moontlikheid as 'n manifestasie van hipersensitiwiteit.

Algemene versteurings en effekte by die plek van toediening:
Die volgende newe-effekte is aangemeld, maar die frekwensies is onbekend: daar mag na intraveneuse toediening pyn op die inspuitplek wees, en tromboflebitis het ná intraveneuse infusie voorgekom. Daar kan 'n positiewe reaksie op die Coombstoets wees.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN
Sien "NEWE-EFFEKTE en "WAARSKUWINGS EN SPESIALE VOORSORGMAATREëLS".
Die vlakke van CEFTAZIDIME 1 g OETHMAAN in die serum word deur dialise verlaag.
Behandeling is ondersteunend en simptomaties.

IDENTIFIKASIE
CEFTAZIDIME 1 g OETHMAAN : 'n wit tot roomkleurige poeier.

AANBIEDING
CEFTAZIDIME 1 g OETHMAAN-poeier vir oplossing vir inspuiting word in kartonne verpak wat 1 of 10 kleurlose glasflessie met 'n enkele dosis bevat met 'n grys rubberprop en aluminiumdoppie met 'n rooi afwipseël.

BEWARINGSINSTRUKSIES
Bewaar in die oorspronklike pakkie (in die karton) teen of benede 25 ºC.
Die aangemaakte oplossing moet onmiddellik gebruik word, maar die oplossing kan vir 24 uur in die oorspronklike flessies in die yskas by 2 tot 8 ºC gebêre word. Gooi alle oorblywende oplossing na gebruik weg.
HOU BUITE DIE BEREIK VAN KINDERS.

REGISTRASIENOMMERS
CEFTAZIDIME 1 g OETHMAAN: 41/20.1.1/0922

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT

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DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET
08 Februarie 2008

1221950-V1