SCHEDULING STATUS: S4

PROPRIETARY NAME AND DOSAGE FORM:

Cefotaxime 0,5 g Oethmaan (powder for solution for injection)
Cefotaxime 1,0 g Oethmaan (powder for solution for injection)
(IM, IV injection or for IV infusion)

COMPOSITION:
Cefotaxime 0,5 g Oethmaan: Each vial contains dry, sterile cefotaxime sodium equivalent to 0,5 g Cefotaxime.
Cefotaxime 1,0 g Oethmaan: Each vial contains dry, sterile cefotaxime sodium equivalent to 1,0 g Cefotaxime.
Sugar free.

PHARMACOLOGICAL CLASSIFICATION:
A 20.1.1 Broad and medium spectrum antibiotics

PHARMACOLOGICAL ACTION:
Cefotaxime is a bactericidal semi-synthetic third-generation cephalosporin. The antibacterial action results from inhibition of bacterial cell wall synthesis by binding to essential target proteins in bacterial cytoplasmic membranes.
Cefotaxime has activity against a wide range of bacterial organisms (Gram positive and Gram-negative), including beta-lactamase producing strains.

Pharmacokinetic properties:
Cefotaxime is metabolized in the liver to both active and inactive metabolites, and is approximately 90 % excreted in the urine. Approximately 30 % of the dose of cefotaxime is excreted unchanged, while 15-25 % is excreted as the desacetyl derivative, the major active metabolite. The mean terminal half-life is about 80 minutes.

IM injection:
Peak plasma levels are reached 30 minutes after IM injection of 0,25 g; 0,5 g and 1 g doses. The peak plasma level attained is dose-dependent-approximately 24 μg/ml after the 1 g injection Urinary excretion is 50 % to 60 % of the administered dose within 24 hours after injection (44 % to 55 % within the first six hours). Cefotaxime crosses the blood-brain barrier.

IV injection:
Initial phase half-life for whole blood and plasma are 4,5 and 8 minutes respectively. Terminal phase half-lives for whole blood and plasma are 1,3 and 2,2 hours respectively. Most of the dose is excreted within 4 hours of dosing. The elimination half-life is prolonged with renal impairment. Between 85 % and 90 % of the administered dose is excreted in the urine and 7 % to 9,5 % is excreted in the faeces. Cefotaxime is metabolized in the liver to active and inactive metabolites. Approximately 20 % to 36 % of an IV dose is excreted as unchanged cefotaxime, while 15 % to 25 % is excreted as the desacetyl derivative, the major active metabolite. Two other inactive urinary metabolites account for 20 % to 25 % of the excreted dose.

IV infusion:
A loading dose of 0,5 g, 1 g, or 2 g, administered over 15 minutes followed by sustaining infusions of 0,5 g, 1 g, or 2 g per hour produces mean peak serum levels of 41 μg/ml, 93 μg/ml or 160 μg/ml respectively. The mean terminal half-life is 75 ± 7 minutes. Most of the administered dose (63 ± 9 %) is renally excreted within 24 hours.

Micro-organisms resistant to cefotaxime:
Most strains of enterococci are resistant.
Most strains of *Clostridium difficile* are resistant.
Pseudomonas aeroginosa, Listeria monocyogenes

INDICATIONS
Cefotaxime 0,5 g Oethmaan and Cefotaxime 1,0 g Oethmaan is indicated for the treatment of infections caused by susceptible strains of organisms in the following infections:-

Upper Respiratory Tract Infections:
- Pneumococcal infections – Pneumonia, bronchitis, cellulites, otitis media
- *Haemophilus influenzae* infections – Otitis media, *Laryngotracheobronchitis*, meningitis (in children)

Urinary tract Infections:
- E. coli infections – Pneumonia, urinary tract infections, meningitis (in children)

Gastrointestinal Infections
- Shigella infections – Bacillary dysentery
- Salmonella infections - Enteritis

Other:
- Neisseria meningitides – Meningitis (in children)
- Acute uncomplicated cystitis caused by E.coli and Klebsiella pneumoniae.

Note: Bacteriological tests to determine causative organisms and sensitives are recommended.

Cefotaxime 0,5 g Oethmaan and Cefotaxime 1,0 g Oethmaan is indicated perioperatively to reduce the incidence of certain post-operative infections in patients undergoing surgical procedures classified as potentially contaminated.

CONTRAINDICATIONS
Hypersensitivity to cefotaxime, cephalosporin antibiotics or to any of the ingredients.
Hypersensitivity to penicillin and other beta-lactam antibiotics.

WARNINGS AND SPECIAL PRECAUTIONS
The sodium content of cefotaxime sodium (48,2 mg/g) should be taken into consideration in patients on sodium restriction.
The white cell count should be monitored for treatment courses of more than 10 days. Treatment should be discontinued in the event of neutropenia. Pseudomembranous colitis has been reported with the use of **Cefotaxime 0,5 g Oethmaan and Cefotaxime 1,0 g Oethmaan.** Patients who develop abdominal or stomach cramps, abdominal tenderness, severe and watery diarrhoea (which may be bloody) and fever, should be investigated for this diagnosis. If the diagnosis of pseudomembranous colitis is suspected, **Cefotaxime 0,5 g Oethmaan and Cefotaxime 1,0 g Oethmaan** should be stopped immediately and appropriate therapy initiated.

Cefotaxime 0,5 g Oethmaan and Cefotaxime 1,0 g Oethmaan should be used with caution in patients with:-
- A history of gastrointestinal disease, especially ulcerative colitis, regional enteritis or antibiotic-associated colitis.
- Renal function impairment – A reduced dose may be required (see "DOSAGE AND DIRECTIONS FOR USE").
- Porphyria: Safety has not been established.

Stop treatment with **Cefotaxime 0,5 g Oethmaan and Cefotaxime 1,0 g Oethmaan** in the event of an allergic reaction. Prolonged use of **Cefotaxime 0,5 g Oethmaan and Cefotaxime 1,0 g Oethmaan** may result in the overgrowth of non-susceptible organisms i.e. superinfection with candida, Enterococci or *Clostridium difficile.*
A Jarisch-Herxheimer reaction may develop during the first few days of treatment with **Cefotaxime 0,5 g Oethmaan and Cefotaxime 1,0 g Oethmaan.** After several weeks of treatment with **Cefotaxime 0,5 g Oethmaan** and **Cefotaxime 1,0 g Oethmaan**, skin rash, itching, fever, leucopenia, increase in liver enzymes, dyspnoea and arthralgia has been reported.

INTERACTIONS
Concurrent administration of potentially nephrotoxic medicines or diuretics may increase the risk of possible nephrotoxicity.
Do not mix **Cefotaxime 0,5 g Oethmaan and Cefotaxime 1,0 g Oethmaan** with another antibiotic in the same syringe or infusion solution.

Interaction with Laboratory Tests:
A positive Coombs reaction appears in patients who receive large doses of **Cefotaxime 0,5 g Oethmaan and Cefotaxime 1,0 g Oethmaan.** Haemolysis is not usually associated with the phenomenon but it may interfere with cross-matching of blood.

Cefotaxime 0,5 g Oethmaan and Cefotaxime 1,0 g Oethmaan may give false-negative tests results with ferricyanide blood glucose test.

A false-positive reaction can occur on testing for glucose in the urine with reducing substances. This can be avoided with the use of methods specific to gluco-oxidase.

HUMAN REPRODUCTION
Safety and efficacy in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE
Dosage, route of administration and frequency of injections depends on the nature and severity of the infection, the condition of the patient and the sensitivity of the pathogens to **Cefotaxime 0,5 g Oethmaan and Cefotaxime 1,0 g Oethmaan.**

Adults:
2 g daily administered as two injections of 1 g.
In severe infections, the dose may be increased to 3 g to 4 g daily given in 2 to 4 administrations. Very severe infections may require a dose of up to 12 g IV.

Children:
Neonates (0 to 1 week of age): 50 mg/kg body weight IV 12-hourly
Neonates (1 to 4 weeks of age): 50 mg/kg body weight IV 8-hourly
Note: It is not necessary to differentiate between premature and normal gestational age infants.

Infants and children: 50 mg/kg to 100 mg/kg body weight administered in 2 to 4 injections.
In exceptional cases, the dose may be increased to 200 mg/kg body weight per day.

Renal function impairment:
Reduce the dose by 50 % in patients with a creatinine clearance of less than 20 ml/minute. Do not alter the dosing interval.

Directions for preparation of injections:
IV and IM injections:
Dissolve **Cefotaxime 0,5 g Oethmaan and Cefotaxime 1,0 g Oethmaan** in Water for Injection (WFI) BP (0,5 g vial in 2 ml WFI; 1 g vial in 4 ml WFI). Shake vial until dissolved. Withdraw the entire contents of the vial into the syringe and use immediately.
Cefotaxime is given as deep intramuscular injection or by slow intravenous injection over 3-5 minutes.

Intravenous infusions:
Dissolve **Cefotaxime 0,5 g Oethmaan and Cefotaxime 1,0 g Oethmaan** 1 g or 2 x 1 g vials in 40 to 100 ml of Water For Injection, 0.9 % sodium chloride, 5 % dextrose or Ringer's solution. The prepared infusion solutions should be freshly prepared and administered over 20-60 minutes.

Stability:
The reconstituted solution should not be stored and any remaining solution should be discarded.

SIDE EFFECTS
Cardiac disorders:
The following side-effects have been reported and the frequencies are unknown: Arrhythmias following rapid bolus infusion through a central venous catheter.

Nervous system disorders:
The following side-effects have been reported and the frequencies are unknown: Headache, confusion, encephalopathy.

Gastrointestinal disorders:
The following side-effects have been reported and the frequencies are unknown: Diarrhoea, nausea, vomiting, abdominal pain.

Renal and urinary disorders:
The following side-effects have been reported and the frequencies are unknown: Decrease in renal function (especially when co-prescribed with aminoglycosides), interstitial nephritis.

Hepatobiliary disorders:
The following side-effects have been reported and the frequencies are unknown: Transient increases in hepatic enzyme levels and/or bilirubin (Values may exceed twice the upper limit of normal and lead to asymptomatic cholestatic liver injury).

Skin and subcutaneous tissue disorders:
The following side-effects have been reported and the frequencies are unknown: Local inflammatory reactions at the injection site, rash, pruritus, urticaria, erythema multiforme, Steven-Johnson syndrome, toxic epidermal necrolysis.

Immune system disorders:
The following side-effects have been reported and the frequencies are unknown: Hypersensitivity reactions including skin rashes, urticaria, pruritus, bronchospasm, drug fever, serum sickness, shock, anaphylaxis.

KNOWN SYMPTOMS OF OVER-DOSAGE AND PARTICULARS OF ITS TREATMENT.
(See "**SIDE EFFECTS and WARNINGS AND SPECIAL PRECAUTIONS**")

Symptoms of overdose:
Encephalopathy (impairment of consciousness, abnormal movements and seizures) has been reported.

Treatment of overdose:
Treatment is symptomatic and supportive.

IDENTIFICATION:
Cefotaxime 0,5 g Oethmaan powder for solution for injection:
White to yellowish powder.

Cefotaxime 1,0 g Oethmaan powder for solution for injection:
White to yellowish powder.
On constitution, a slightly yellow to brownish yellow clear solution is obtained.

PRESENTATIONS:
Packs for IM, IV injection or for IV infusion containing:

Cefotaxime 0,5 g Oethmaan powder for solution for injection:
15 ml single dose, colourless glass vials with a grey rubber stopper and aluminium cap with a golden yellow flip-off seal packed in cartons of ones or 10's.

Cefotaxime 1,0 g Oethmaan powder for solution for injection:
20 ml single dose, colourless glass vials with a grey rubber stopper and aluminium cap with a green flip-off seal packed in cartons of ones or 10's.

STORAGE INSTRUCTIONS:
Store in the original packaging (in the carton) at or below 25 °C.
The reconstituted solution is intended for immediate use and any remaining solution must be discarded after use.

KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER:
Cefotaxime 0,5 g Oethmaan: 41/20.1.1/1063
Cefotaxime 1,0 g Oethmaan: 41/20.1.1/1064

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EIENDOMSNAAM EN DOSEERVORM
Cefotaxime 0,5 g Oethmaan (poeier vir oplossing vir inspuiting)
Cefotaxime 1 g Oethmaan (poeier vir oplossing vir inspuiting)
(IM-, IV-inspuiting of vir IV-infusie)

SAMESTELLING
Cefotaxime 0,5 g Oethmaan: Elke flessie bevat droë, steriele natrium-kefotaksiem gelykstaande aan 0,5 g kefotaksiem.
Cefotaxime 1 g Oethmaan: Elke flessie bevat droë, steriele natrium-kefotaksiem gelykstaande aan 1,0 g kefotaksiem.

Suikervry.

FARMAKOLOGIESE KLASSIFIKASIE
A 20.1.1 Breë- en mediumspektrumantibiotika

FARMAKOLOGIESE WERKING
Kefotaksiem is 'n bakterisidiese semisintetiese derdegenerasie kefalosporien. Die antibakteriële werking is die gevolg van remming van bakteriële selwandsintese deur binding aan essensiële teikenproteïene in die membrane van bakteriële sitoplasma.
Kefotaksiem het aktiwiteit teen 'n wye verskeidenheid bakteriële organismes (Gram-positief en Gram-negatief), waaronder beta-laktamaseproduserende stamme ingesluit is.

Farmakokinetiese eienskappe
Kefotaksiem word in die lewer na sowel aktiewe as onaktiewe metaboliete gemetaboliseer, en ongeveer 90 % word in die urien uitgeskei. Ongeveer 30 % van die dosis kefotaksiem word onveranderd uitgeskei, terwyl 15-25 % as die desasetielderivaat, die hoof aktiewe metaboliet, uitgeskei word. Die gemiddelde terminale halfleeftyd is ongeveer 80 minute.

IM-Inspuiting
Piek plasmavlakke word 30 minute na IM-inspuiting van dosisse van 0,25 g, 0,5 g of 1 g bereik. Die piek plasmavlak wat bereik word, is dosis afhanklik ongeveer 24 µg / ml na die inspuiting van 1 g. Urinêre uitskeiding is 50 tot 60 % van die toegediende dosis binne 24 uur na die inspuiting (44 tot 55 % binne die eerste ses uur). Kefotaksiem kruis die bloedbreinskans.

IV-Inspuiting
Halfleeftye van die aanvangsfases vir volbloed en plasma is onderskeidelik 4,5 en 8 minute. Die halfleeftyd van die terminale fase in volbloed en in plasma is 1,3 en 2,2 uur onderskeidelik. Die grootste deel van die dosis word binne 4 uur na toediening uitgeskei. Die eliminasiehalfleeftyd is langer in pasiënte met swak nierfunksie. Tussen 85 en 90 % van die toegediende dosis word in die urien en 7 tot 9,5 % in die feses uitgeskei. Kefotaksiem word in die lewer na aktiewe metaboliete gemetaboliseer. Ongeveer 20 tot 36 % van 'n IV-dosis word as onveranderde kefotaksiem uitgeskei, terwyl 15 tot 25 % as die desasetielderivaat, die hoof aktiewe metaboliet, uitgeskei word. Twee ander onaktiewe urinêre metaboliete bedra 20 tot 25 % van die uitgeskeide dosis.

IV-Infusie
'n Ladingsdosis van 0,5 g, 1 g of 2 g oor 15 minute gevolg deur volgehoue infusie van 0,5 g, 1 g of 2 g per uur gee gemiddelde piek serumvlakke van 41 µg/ml, 93 µg/ml of 160 µg/ml onderskeidelik. Die gemiddelde terminale halfleeftyd is 75 ± 7 minute. Die grootste deel van die toegediende dosis (63 ± 9 %) word binne 24 uur deur die niere uitgeskei.

Mikro-organismes wat weerstandig teenoor kefotaksiem is
Die meeste stamme enterokokke is bestand.
Die meeste stamme van *Clostridium difficile* is bestand.
Pseudomonas aeruginosa, Listeria monocytogenes.

INDIKASIES
Cefotaxime 0,5 g Oethmaan en Cefotaxime 1 g Oethmaan is aangedui vir die behandeling van infeksies veroorsaak deur vatbare stamme van die volgende organismes tydens die volgende infeksies:

Boonstelugweginfeksies
- Pneumokokkale *infeksies* – Longontsteking, brongitis, sellulitis, otitis media
- *Haemophilus influenzae-infeksies*-Otitis media,Laringotrageobrongitis, meningitis (in kinders)

Urienweginfeksies
- Infeksies deur E. coli – Longontsteking, urienweginfeksies, meningitis (in kinders)

Gastro-intestinale infeksies
- Shigella-infeksies – Basillêre disenterie
- Salmonella-infeksies – Enteritis

Ander
- Neisseria meningitides – meningitis (in kinders)
- Akute ongekompliseerde sistitis veroorsaak deur *E. coli en Klebsiella pneumoniae*

Let wel: Bakteriologiese toetse om veroorsakende organismes en sensitiwiteit te bepaal word aanbeveel.

Cefotaxime 0,5 g Oethmaan en Cefotaxime 1 g Oethmaan is peri-operatief aangedui om die voorkoms van sekere postoperatiewe infeksies te verminder in pasiënte wat chirurgiese prosedures ondergaan wat as potensieel besmet geklassifiseer is.

KONTRA-INDIKASIES
Hipersensitiwiteit teenoor kefotaksiem, kefalosporienantibiotika of enige van die bestanddele.

Hipersensitiwiteit teenoor penisillien en ander beta-laktaamantibiotika.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREëLS
Die natriuminhoud van natriumkefotaksiem (48,2 mg/g) moet in ag geneem word vir pasiënte op beperkte natrium.

Die witbloedseltelling moet gemonitor word tydens behandelings van meer as 10 dae. Indien neutropenie ontstaan, moet behandeling gestaak word. Pseudomembraankolitis is aangemeld met die gebruik van **Cefotaxime 0,5 g Oethmaan** en **Cefotaxime 1 g Oethmaan.** Pasiënte wat krampe op die buik of maag, abdominale teerheid, erge en waterige diarree (wat bloederig kan wees) en koors ontwikkel, moet vir hierdie diagnose ondersoek word. As pseudomembraankolitis vermoed word, moet **Cefotaxime 0,5 g Oethmaan en Cefotaxime 1 g Oethmaan** onmiddellik gestaak en geskikte behandeling gegee word.

Cefotaxime 0,5 g Oethmaan en Cefotaxime 1 g Oethmaan moet versigtig gebruik word in pasiënte met:
- 'n Geskiedenis van gastro-intestinale siekte, veral ulseratiewe kolitis, regionale enteritis en kolitis vanweë antibiotika.
- Swak nierfunksie - 'n laer dosis mag nodig wees (sien "DOSIS EN GEBRUIKSAANWYSINGS").
- Porfirie:Die veiligheid is nie bepaal nie.

Stop behandeling met **Cefotaxime 0,5 g Oethmaan en Cefotaxime 1 g Oethmaan** in die geval van 'n allergiese reaksie. Langdurige gebruik van **Cefotaxime 0,5 g Oethmaan** en **Cefotaxime 1 g Oethmaan** kan tot die oorgroei van nie-vatbare organismes lei, d.i. superinfeksies deur *Candida,* enterokokke of *Clostridium difficile.*

'n Jarisch-Herxheimerreaksie kan in die eerste paar dae van behandeling met **Cefotaxime 0,5 g Oethmaan** en **Cefotaxime 1 g Oethmaan** ontwikkel. Veluitslag, jeuk, koors, leukopenie, styging in vlakke van lewerensieme, dispnee en artralgie is na etlike weke van behandeling met **Cefotaxime 0,5 g Oethmaan** en **Cefotaxime 1 g Oethmaan** aangemeld.

INTERAKSIES
Gelyktydige toediening van potensieel nefrotoksiese medisyne of diuretika mag die risiko vir moontlike nefrotoksisiteit verhoog.
Cefotaxime 0,5 g Oethmaan en Cefotaxime 1 g Oethmaan moet nie saam met 'n ander antibiotikum in dieselfde spuit of infusie-oplossing gemeng word nie.

Interaksie met laboratoriumtoetse
Pasiënte wat groot dosisse **Cefotaxime 0,5 Oethmaan** en **Cefotaxime 1 g Oethmaan** ontvang, kan 'n positiewe Coombsreaksie gee. Hemolise kom nie gewoonlik saam met die verskynsel voor nie, maar dit kan met versoenbaarheidstoetse van bloed inmeng.

Cefotaxime 0,5 g Oethmaan en Cefotaxime 1 g Oethmaan kan vals negatiewe resultate met die ferrisianiedtoets vir bloedglukose gee.

'n Vals positiewe reaksie kan voorkom met reduserende stowwe vir die toets van glukose in die urien. Dit kan vermy word met gebruik van metodes wat spesifiek vir gluko-oksidase is.

MENSLIKE VOORTPLANTING
Die veiligheid en effektiwiteit tydens swangerskap en borsvoeding is nie bepaal nie.

DOSIS EN GEBRUIKSAANWYSINGS
Die dosis, toedieningsroete en frekwensie van inspuitings hang af van die aard en erns van die infeksie, die toestand van die pasiënt en die sensitiwiteit van die patogene vir **Cefotaxime 0,5 g Oethmaan** en **Cefotaxime 1 g Oethmaan.**

Volwassenes
2 g daagliks toegedien as twee inspuitings van 1 g elk.
Vir ernstige infeksies kan die dosis na 3-4 g per dag met 2 tot 4 toedienings verhoog word. Vir baie ernstige infeksies kan 'n dosis van tot 12 g IV nodig wees.

Kinders
Pasgeborenes (0 tot 1 week oud): 50 mg/kg liggaamsgewig IV elke 12 uur
Pasgeborenes (1 tot 4 week oud): 50 mg/kg liggaamsgewig IV elke 8 uur
Let wel:Dit is nie nodig om onderskeid te tref tussen premature en voltydbabas nie.

Babas en kinders: 50 tot 100 mg/kg liggaamsmassa toegedien met 2 tot 4 inspuitings.
In uitsonderlike gevalle kan die dosis na 200 mg/kg liggaamsgewig per dag verhoog word.

Swak nierfunksie:
Verlaag die dosis met 50 % vir pasiënte met kreatinienopruiming minder as 20 ml/min. Moenie die doseerinterval verander nie.

Aanwysings vir die bereiding van inspuitings
IV- en IM-inspuitings
Los **Cefotaxime 0,5 g Oethmaan en Cefotaxime 1 g Oethmaan** op in water vir inspuiting (WVI) BP (0,5 g-flessie in 2 ml WVI; 1 g-flessie in 4 ml WVI). Skud die flessie totdat dit opgelos is. Onttrek die volle inhoud van die flessie in die spuit en gebruik dadelik.
Kefotaksiem word as 'n diep intramuskulêre inspuiting gegee of deur 'n stadige intraveneuse inspuiting oor 3-5 minute.

Intraveneuse infusies
Los die inhoud van 1 of 2 **Cefotaxime 1 g Oethmaan** op in 40 tot 100 ml water vir inspuiting, 0,9 % natriumchloried, 5 % dekstrose of Ringer se oplossing. Die aangemaakte oplossings vir infusie moet vars berei en oor 20 tot 60 minute gegee word.

Stabiliteit
Die aangemaakte oplossing moet nie gebêre word nie en alle oorblywende oplossing moet weggegooi word.

NEWE-EFFEKTE
Hartversteurings
Die volgende newe-effekte is aangemeld, maar die frekwensies is onbekend: aritmie na vinnige bolusinfusie deur 'n sentrale veneuse kateter.

Versteurings van die senustelsel
Die volgende newe-effekte is aangemeld, maar die frekwensies is onbekend: hoofpyn, verwardheid, enkefalopatie.

Gastro-intestinale versteurings
Die volgende newe-effekte is aangemeld, maar die frekwensies is onbekend: diarree, naarheid, braking, buikpyn

Versteurings van die niere en urienweg
*Die volgende newe-effekte is aangemeld, maar die frekwensies is onbekend:*Afname in nierfunksie (veral wanneer saam met aminoglikosiede voorgeskryf word), interstisiële nefritis.

Hepatobilifère versteurings
Die volgende newe-effekte is aangemeld, maar die frekwensies is onbekend: Verbygaande stygings in vlakke van lewerensiemvlakke en/of bilirubien (waardes kan twee keer die boonste limiet van normaal oorskry en tot asimptomatiese cholestatiese lewerskade lei).

Versteurings van die vel en subkutane weefsel
Die volgende newe-effekte is aangemeld, maar die frekwensies is onbekend: Lokale inflammatoriese reaksies by die inspuitplek, uitslag, pruritus, urtikarie, multivorme eriteem, Stevens-Johnsonsindroom, toksiese epidermale nekrolise.

Versteurings van die immuunstelsel
*Die volgende newe-effekte is aangemeld, maar die frekwensies is onbekend:*Hipersensitiwiteitsreaksies waaronder veluitslag, urtikarie, pruritus, brongospasma, geneesmiddelkoors, serumsiekte, skok, anafilakse.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN
(Sien **"NEWE-EFFEKTE"** en **WAARSKUWINGS EN SPESIALE VOORSORGMAATREëLS**).

Simptome van oordosering
Enkefalopatie (inkorting van bewussyn, abnormale bewegings en toevalle) is aangemeld.

Behandeling van oordosering
Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE
Cefotaxime 0,5 g Oethmaan (poeier vir oplossing vir inspuiting):wit tot gelerige poeier.

Cefotaxime 1,0 g Oethmaan (poeier vir oplossing vir inspuiting):wit tot gelerige poeier.
Na aanmaak word 'n helder effens geel tot bruin-geel oplossing verkry.

AANBIEDINGS
Pakke vir IM-, IV-inspuiting of vir IV-infusie wat die volgende bevat:

Cefotaxime 0,5 g Oethmaan poeier vir oplossing vir inspuiting:
'n Kleurlose, 15 ml glasflessie met 'n grys rubberprop en aluminiumdoppie met'n goud geel afwipseël wat as 1 of 10 per kartonhouer verpak is.

Cefotaxime 1 g Oethmaan poeier vir oplossing vir inspuiting:
'n Kleurlose, 20 ml glasflessie met 'n grys rubberprop en aluminiumdoppie met 'n groen afwipseël wat as 1 of 10 per kartonhouer verpak is.

BERGINGSINSTRUKSIES
Bewaar in die oorspronklike pakkie (in die karton) teen of benede 25 °C. Die aangemaakte oplossing is bedoel vir onmiddellike gebruik en alle oorblywende oplossing moet na gebruik weggegooi word.

HOU BUITE DIE BEREIK VAN KINDERS.

REGISTRASIENOMMER
Cefotaxime 0,5 g Oethmaan: 41/20,1.1/1063
Cefotaxime 1,0 g Oethmaan: 41/20,1.1/1064

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