AUROXIME
P1530212

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P1530212

SKEDULERINGSTATUS

SUID AFRIKA: S4

NAMIBIË: NS2

EIENDOMSNAAM (en doseervorm):
AUROXIME TABLETS 125 mg (tablet)
AUROXIME TABLETS 250 mg (tablet)
AUROXIME TABLETS 500 mg (tablet)

SAMESTELLING:
AUROXIME TABLETS 125 mg: Elke tablet bevat kefuroksiemaksetiel (amorf) ekwivalent aan 125 mg kefuroksiem. Suikervry.
AUROXIME TABLETS 250 mg: Elke tablet bevat kefuroksiemaksetiel (amorf) ekwivalent aan 250 mg kefuroksiem. Suikervry.
AUROXIME TABLETS 500 mg: Elke tablet bevat kefuroksiemaksetiel (amorf) ekwivalent aan 500 mg kefuroksiem. Suikervry.

Die ander bestanddele is mikrokristallyne sellulose, kroskarmellose natrium, gehidrogeneerde plantolie, kolloïdale anhidriese silika en natriumlourielsulfaat.

FARMAKOLOGIESDE KLASSIFIKASIE:
A 20.1.1 Breë- en mediumspektrum antibiotika

FARMAKOLOGIESE WERKING:
Kefuroksiem is 'n bakteriedodende tweede-generasie kefalosporien. Die antibakteriese werking van kefuroksiem is die gevolg van inhibisie van bakteriële selwandsintese deur binding aan essensiële teikenproteïene in bakteriële sitoplasmiese membrane. Kefuroksiem besit bakteriedodende aktiwiteit teen 'n wye reeks van bakteriese organismes, insluitende beta-laktamaseproduserende stamme.

Farmakokinetika
Kefuroksiemaksetiel is 'n promiddel van kefuroksiem. Na orale absorpsie word kefuroksiemaksetiel in die intestinale slymvlies en bloed gehidroliseer om kefuroksiem in die plasma vry te stel. Orale absorpsie is optimaal wanneer dit saam met voedsel toegedien word. Piek serumvlakke van kefuroksiem kom gewoonlik 2 tot 3 ure na orale dosering voor wanneer dit saam voedsel geneem word. Proteïenbinding is ongeveer 33 % tot 50 %. Kefuroksiem word nie gemetaboliseer nie en word deur glomerulêre filtrasie en buissekresie onveranderd in die urien uitgeskei. Die eliminasiehalfleeftyd is tussen 1 en 1,5 ure na orale dosering. Die eliminasiehalfleeftyd word met ingekorte nierfunksie verleng. Serumvlakke van kefuroksiem word met dialise verminder.

INDIKASIES:

AUROXIME TABLETS word aangedui vir die behandeling van infeksies wat deur vatbare stamme van die volgende organismes in die volgende infeksies veroorsaak word:
- Faringitis en tonsilitis veroorsaak deur *Streptococcus pyogenes.*
- Otitis media veroorsaak deur *Streptococcus pneumoniae, Haemophilus influenzae* (ampisilliensensitiewe en –weerstandbiedende stamme), *Moraxella (Branhamella) catarrhalis* en *Streptococcus pyogenes.*
- Sinusitis veroorsaak deur *Streptococcus pneumoniae* en *Haemophilus influenzae.*
- Akute en chroniese brongitis veroorsaak deur *Streptococcus pneumoniae, Haemophilus influenzae* (ampisilliensensitiewe stamme) en *Haemophilus parainfluenzae* (ampisilliensensitiewe stamme).
- Akute ongekompliseerde sistitis veroorsaak deur *Escherichia coli* en *Klebsiella pneumoniae.*
- Lyme se siekte veroorsaak deur *Borrelia burgdorferi.*

KONTRA-INDIKASIES:
- Hipersensitiwiteit teen kefalosporienantibiotika of teen enige van die bestanddele van die formulasie.
- Hipersensitiwiteit teen penisillien en ander betalaktaamantibiotika.

WAARSKUWINGS EN SPESIALE VOORSORGSMAATREËLS:

AUROXIME TABLETS behoort met sorg in die volgende pasiënte gebruik te word:
- Pasiënte met 'n geskiedenis van gastroïntestinale siekte, veral ulseratiewe kolitis, streekenteritis of pseudomembraneuse kolitis.
- Pasiënte met ingekorte nierfunksie – 'n Laer dosis mag nodig wees.
- Pasiënte met porfirie: Die veiligheid is nie vasgestel nie.

Pseudomembraneuse kolitis kan voorkom. Mense wat buik- of maagkrampe, buikteerheid, erge en waterige diaree (wat bloederig mag wees) en koors ontwikkel, behoort vir hierdie diagnose ondersoek te word. Indien die diagnose van pseudomembraneuse kolitis vermoed word, behoort die gebruik van **AUROXIME TABLETS** onmiddellik gestaak en die toepaslike terapie ingestel te word.

Jarisch-Hexheimer se reaksie is na behandeling met **AUROXIME TABLETS** vir Lyme se siekte aangemeld. Die reaksie is 'n algemene en gewoonlik selfbeperkende gevolg van antibiotikabehandeling van Lyme se siekte.

Die verlengde gebruik van **AUROXIME TABLETS** mag tot die oorgroeiing van nie-vatbare organismes (bv. Candida, Enterokokke en *Clostridium difficile*) lei.

INTERAKSIES:
Die gelyktydige toediening van probenesied verhoog die area onder die gemiddelde konsentrasie-tydkurwe met 50 %.

Interaksies met laboratoriumtoetse:
Daar word aanbeveel dat glukoseöksidase- of heksokinasemetodes gebruik word om glukosevlakke in die bloed/plasma te bepaal in pasiënte wat **AUROXIME TABLETS** ontvang.

Hierdie medisyne kan vals-negatiewe toetsresultate met die ferrisianied bloedglukosetoets lewer. **AUROXIME TABLETS** meng nie in met die alkaliese pikraatbepaling vir kreatinien nie.

'n Vals-positiewe Coombsreaksie kan in pasiënte wat groot dosisse **AUROXIME TABLETS** neem, ontwikkel.

SWANGERSKAP EN LAKTASIE:
Die veiligheid en effektiwiteit in swangerskap en laktasie is nie vasgestel nie.

DOSIS EN GEBRUIKSAANWYSINGS:

Volwassenes:

Sinusitis en akute of chroniese brongitis:
250 mg twee keer per dag vir sewe dae (reikwydte 5 – 10 dae)

Akute, ongekompliseerde sistitis:
125 mg twee keer per dag vir sewe dae (reikwydte 5 – 10 dae)

Lyme se siekte:
Volwassenes en kinders ouer as 12 jaar oud: 500 mg twee keer per dag vir 20 dae

Kinders:
Daar bestaan geen ondervinding van **AUROXIME TABLETS** in kinders jonger as 3 maande oud nie.
- 3 maande tot 2 jaar oud: 125 mg twee keer per dag.
- Ouer as 2 jaar: 250 mg twee keer per dag.

Vir optimum absorpsie behoort **AUROXIME TABLETS** 'n halfuur na 'n maaltyd geneem te word.

NEWE EFFEKTE:

Afwykings van die bloed-en limfsisteem:
Baie dikwels: Eosinofilie.

Afwykings van die senuweestelsel:
Die volgende newe effekte is aangemeld en die frekwensies is onbekend: Hoofpyn.

Gastroïntestinale afwykings:
Dikwels: Naarheid, braking, buikpyn, diaree wat in sommige gevalle gepaard gaan met bloed in die stoelgang, wat 'n teken van enterokolitis kan wees. 'n Spesifieke vorm van enterokolitis is pseudomembraneuse kolitis (sien **"WAARSKUWINGS EN SPESIALE VOORSORGSMAATREËLS"**).

Geslagstelsel- en borsafwykings:
Die volgende newe effekte is aangemeld en die frekwensies is onbekend: Vaginale kandidiase.

Ondersoeke:
Die volgende newe effekte is aangemeld en die frekwensies is onbekend: Verbygaande toename in lewerensiemvlakke.

Afwykings van die vel en sagte weefsel:
Dikwels: Erythema multiforme, Stevens-Johnson se sindroom en toksiese dermale nekrolise.

Afwykings van die immuunstelsel:
Dikwels: Hipersensitiwiteitsreaksies insluitende veluitslag, urtikarie, pruritus, bronchospasma, geneesmiddelkoors, serumsiekte, anafilakse.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
(Sien **"NEWE EFFEKTE"**)

Simptome van oordosering:
Stuipaanvalle is aangemeld.

Behandeling van oordosering:
Behandeling is simptomaties en ondersteunend. Serumvlakke van **AUROXIME TABLETS** kan met hemodialise of peritoneale dialise verminder word.

IDENTIFIKASIE:
AUROXIME TABLETS 125 mg: Wit tot byna-wit, filmbedekte kapsulevormige tablette met 'A32' aan die een kant gedruk en ongedruk aan die ander kant.
AUROXIME TABLETS 250 mg: Wit tot byna-wit, filmbedekte kapsulevormige tablette met 'A33' aan die een kant gedruk en ongedruk aan die ander kant.
AUROXIME TABLETS 500 mg: Wit tot byna-wit, filmbedekte kapsulevormige tablette met 'A34' aan die een kant gedruk en ongedruk aan die ander kant.

AANBIEDING:
AUROXIME TABLETS 125 mg/ 250 mg/500 mg

1. PVC/ACLAR-ALUMINIUM
Tablette word in 250 mikron helder PVC, gelamineer met 23 mikron Aclar as die vormingsmateriaal en 25 mikron aluminiumfoelie as dekmateriaal verpak.

2. ALU-ALU PAK
Tablette word in koudgevormde laminaat verpak: 25 mikron poliamied /45 mikron aluminiumfoelie/60 mikron PVC film as die vormingsmateriaal en 25 mikron aluminiumfoelie as dekmateriaal.

Pakgrotte: 10s- Elke stolpstrokie bevat 10 tablette.

BERGINGSINSTRUKSIES:
Bewaar by of benede 30 °C. Moenie uit die verpakking verwyder tot voor gebruik nie.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:

SUID-AFRIKA:
AUROXIME TABLETS 125 mg: A40/20.1.1/0725
AUROXIME TABLETS 250 mg: A40/20.1.1/0720
AUROXIME TABLETS 500 mg: A40/20.1.1/0721

NAMIBIË:
AUROXIME TABLETS 125 mg: 08/2.1.1/0013
AUROXIME TABLETS 250 mg: 08/2.1.1/0014
AUROXIME TABLETS 500 mg: 08/2.1.1/0015

NAAM EN ADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE
Aurogen South Africa (Edms.) Bpk.
Woodhill Kantoorpark, Gebou 1, Eerste vloer,
Phillip Engelbrechtlaan 53
Meyersdal, Uitbr. 12
1448, Johannesburg
Suid Afrika

DATUM VAN PUBLIKASIE VAN DIE VOUBILJET
Datum van registrasie:
5 Oktober 2007

Datum van hersiening:
18 September 2021

DETACH BEFORE DISPENSING

Stel u dokter in kennis as u enige van die volgende neweeffekte waarneem:
- duiseligheid
- hiperaktiwiteit
- hoofpyn
- senuweeagtigheid
- tekort aan slaap of moeite om aan die slaap te raak
- verwardheid
- lomerigheid of slaapsug
- naarheid
- braking, diaree, buikpyn

Nie al die newe effekte wat vir hierdie medisyne aangemeld is, word in hierdie brosjure ingesluit nie. As u algemene gesondheid agteruitgaan of as u enige ongewone effekte ondervind terwyl u neem, moet u asseblief u dokter, apteker of ander professionele gesondheidswerker om advies raadpleeg.

6. OPBERGING EN WEGDOEN VAN AUROXIME TABLETS

Berg alle medisyne buite die bereik en sig van kinders.
Bewaar by of benede 30 °C. Moenie uit die verpakking haal tot voor gebruik nie.

Neem alle ongebruikte medisyne na u apteker terug.

Moenie enige ongebruikte medisyne in die drein of riolering (bv. toilette) weggooi nie.

7. AANBIEDING VAN AUROXIME TABLETS

1. PVC/ACLAR-ALUMINIUM
Tablette word in 250 mikron helder PVC, gelamineer met 23 mikron Aclar as die vormingsmateriaal en 25 mikron aluminiumfoelie as dekmateriaal verpak.

2. ALU/ALU PAK
Tablette word in koudgevormde laminaat verpak: 25 mikron poliamied /45 mikron aluminiumfoelie/60 mikron PVC film as die vormingsmateriaal en 25 mikron aluminiumfoelie as dekmateriaal.

Pakgrotte: 10s - Elke stolpstrokie bevat 10 tablette.

8. IDENTIFIKASIE VAN AUROXIME TABLETS

AUROXIME TABLETS 125 mg: Wit tot byna-wit, filmbedekte kapsulevormige tablette met 'A32' aan die een kant gedruk en ongedruk aan die ander kant.
AUROXIME TABLETS 250 mg: Wit tot byna-wit, filmbedekte kapsulevormige tablette met 'A33' aan die een kant gedruk en ongedruk aan die ander kant.
AUROXIME TABLETS 500 mg: Wit tot byna-wit, filmbedekte kapsulevormige tablette met 'A34' aan die een kant gedruk en ongedruk aan die ander kant.

9. REGISTRASIENOMMER / VERWYSINGSNOMMER

SUID-AFRIKA:
AUROXIME TABLETS 125 mg: A40/20.1.1/0725
AUROXIME TABLETS 250 mg: A40/20.1.1/0720
AUROXIME TABLETS 500 mg: A40/20.1.1/0721

NAMIBIË:
AUROXIME TABLETS 125 mg: 08/2.1.1/0013
AUROXIME TABLETS 250 mg: 08/2.1.1/0014
AUROXIME TABLETS 500 mg: 08/2.1.1/0015

10. NAAM EN ADRES VAN DIE REGISTRASIEHOUER
Aurogen South Africa (Edms.) Bpk.
Woodhill Kantoorpark, Gebou 1, Eerste vloer,
Phillip Engelbrechtlaan 53
Meyersdal, Uitbr. 12
1448, Johannesburg
Suid Afrika

11. DATUM VAN PUBLIKASIE

Datum van registrasie:
5 Oktober 2007

Datum van hersiening:
18 September 2021

SUID AFRIKA: S4

NAMIBIË: NS2

AUROXIME TABLETS 125 mg (tablet)
AUROXIME TABLETS 250 mg (tablet)
AUROXIME TABLETS 500 mg (tablet)
Kefuroksiemaksetiel

Lees die hele brosjure sorgvuldig voordat u begin om AUROXIME TABLETS te neem.
- Hou hierdie blaadjie. U mag dit moontlik weer wil lees.
- Indien u enige verdere vrae het, moet u asseblief u dokter of apteker raadpleeg.
- **AUROXIME TABLETS** is vir u persoonlik voorgeskryf en u behoort nie u medisyne met ander mense te deel nie. Dit mag hulle skade aandoen, ook al het hulle dieselfde simptome as u.

1. WAT AUROXIME TABLETS BEVAT

Die aktiewe bestanddeel is kefuroksiemaksetiel.

AUROXIME TABLETS 125 mg: Elke tablet bevat kefuroksiemaksetiel (amorf) ekwivalent aan 125 mg kefuroksiem. Suikervry.
AUROXIME TABLETS 250 mg: Elke tablet bevat kefuroksiemaksetiel (amorf) ekwivalent aan 250 mg kefuroksiem. Suikervry.
AUROXIME TABLETS 500 mg: Elke tablet bevat kefuroksiemaksetiel (amorf) ekwivalent aan 500 mg kefuroksiem. Suikervry.

Die ander bestanddele is mikrokristallyne sellulose, kroskarmellose natrium, gehidrogeneerde plantolie, kolloïdale anhidriese silika en natriumlourielsulfaat.

2. WAARVOOR AUROXIME TABLETS GEBRUIK WORD

AUROXIME TABLETS word gebruik om die volgende te behandel:
- Faringitis en tonsilitis veroorsaak deur *Streptococcus pyogenes.*
- Otitis media veroorsaak deur *Streptococcus pneumoniae, Haemophilus influenzae* (ampisilliensensitiewe en –weerstandbiedende stamme), *Moraxella (Branhamella) catarrhalis* en *Streptococcus pyogenes.*
- Sinusitis veroorsaak deur *Streptococcus pneumoniae* en *Haemophilus influenzae.*
- Akute en chroniese brongitis veroorsaak deur *Streptococcus pneumoniae, Haemophilus influenzae* (ampisilliensensitiewe stamme) en *Haemophilus parainfluenzae* (ampisilliensensitiewe stamme).
- Akute ongekompliseerde sistitis veroorsaak deur *Escherichia coli* en *Klebsiella pneumoniae.*
- Lyme se siekte veroorsaak deur *Borrelia burgdorferi.*

3. VOORDAT U AUROXIME TABLETS NEEM

Moenie AUROXIME TABLETS neem nie:
- As u hipersensitief (allergies) teen kefurokssiemaksetiel of enige van die ander bestanddele van **AUROXIME TABLETS** is.
- As u hipersensitief (allergies) teen penisillien en ander betalaktaamantibiotika is.

Neem spesiale sorg met AUROXIME TABLETS:
- As u 'n geskiedenis van gastroïntestinale siekte, veral ulseratiewe kolitis, streekenteritis of pseudomembraneuse kolitis het.
- As u aan nierprobleme ly.
- As u aan porfirie ly - die veiligheid is nie vasgestel nie.
- Pseudomembraneuse kolitis kan voorkom. Mense wat buik- of maagkrampe, buikteerheid, erge en waterige diaree (wat bloederig mag wees) en koors ontwikkel, behoort vir hierdie diagnose ondersoek te word. Indien die diagnose van pseudomembraneuse kolitis vermoed word, behoort die gebruik van **AUROXIME TABLETS** onmiddellik gestaak en die toepaslike terapie ingestel te word.
- Stel u dokter in kennis as u aan sifilis ly, aangesien Jarisch-Herxheimer se reaksie kort nadat daar met die behandeling met **AUROXIME TABLETS** begin word, kan voorkom. Simptome van hierdie reaksie sluit koors, kouekoors en hoofpyn in.

Bestuur en die gebruik van masjinerie:
Die vermoë om te bestuur of met masjinerie te werk kan met **AUROXIME TABLETS** voorkom. Dit geld veral in kombinasie met alkohol.

Die neem van AUROXIME TABLETS met voedsel:
Neem **AUROXIME TABLETS** 'n halfuur na 'n maaltyd.

Swangerskap en borsvoeding:
Stel u dokter in kennis as u swanger is, beplan om swanger te raak of as u borsvoed.
Die veiligheid gedurende swangerskap en laktasie is nie vasgestel nie

As u swanger is of u baba borsvoed, moet u asseblief u dokter, apteker of ander gesondheidsbeampte vir advies nader.

Die neem van ander medisyne saam met AUROXIME TABLETS:
Daar bestaan 'n interaksie tussen **AUROXIME TABLETS** en probenesied.

Probenesied verminder die nieruitskeiding van kefuroksiem.

Stel altyd u dokter in kennis as u enige ander medisyne gebruik.
(Dit sluit komplementêre en tradisionele medisyne in).

4. HOE OM TE AUROXIME TABLETS NEEM

Neem **AUROXIME TABLETS** altyd presies soos deur u dokter voorgeskryf. Bevestig met u dokter of apteker as u onseker is. As u van mening is dat die effek van **AUROXIME TABLETS** te sterk of te swak is, moet u u dokter of apteker raadpleeg.

U dokter sal op grond van u kondisie die toepaslike dosis voorskryf.

As u te veel AUROXIME TABLETS geneem het:
Die simptome van oordosering kan stuipaanvalle, erge buikkrampe en braking insluit

In die geval van oordosering, raadpleeg u dokter of apteker. As hulle nie beskikbaar is nie, kontak u naaste hospitaal of giftbeheersentrum.

As u vergeet het om AUROXIME TABLETS te neem:
As u vergeet het om 'n dosis van u medisyne te neem, moet u dit so gou as u daarvan onthou, neem. As dit egter byna tyd vir die volgende dosis is, moet u die oorgeslaande dosis oorslaan en met die normale dosisskedule voortgaan. Moenie die dosis verdubbel om vir 'n oorgeslaande op te maak nie.

5. MOONTLIKE NEWE EFFEKTE

AUROXIME TABLETS kan newe effekte hê.

As enige van die volgende gebeur, moet u onmiddellik met die gebruik van **AUROXIME TABLETS** ophou en u dokter in kennis sel of na die ongevalle-afdeling van u naaste hospitaal gaan.
- Anaflakse wat deur veluitslag, urtikarie, moeite met asemhaling, swelling van u gesig, lippe, tong, keel en/of skok gekenmerk word.
- Pseudomembraneuse kolitis (buikkrampe, waterige erge diaree, koors).

SCHEDULING STATUS

SOUTH AFRICA: S4

NAMIBIA: NS2

PROPRIETARY NAME (and dosage form):
AUROXIME TABLETS 125 mg (tablet)
AUROXIME TABLETS 250 mg (tablet)
AUROXIME TABLETS 500 mg (tablet)

COMPOSITION:
AUROXIME TABLETS 125 mg: Each tablet contains cefuroxime axetil (amorphous) equivalent to 125 mg cefuroxime. Sugar free.
AUROXIME TABLETS 250 mg: Each tablet contains cefuroxime axetil (amorphous) equivalent to 250 mg cefuroxime. Sugar free.
AUROXIME TABLETS 500 mg: Each tablet contains cefuroxime axetil (amorphous) equivalent to 500 mg cefuroxime. Sugar free.

The other ingredients are microcrystalline cellulose, croscarmellose sodium, hydrogenated vegetable oil, silica colloidal anhydrous and sodium lauril sulfate.

PHARMACOLOGICAL CLASSIFICATION:
A 20.1.1 Broad and medium spectrum antibiotics

PHARMACOLOGICAL ACTION:
Cefuroxime is a bactericidal second-generation cephalosporin. The antibacterial action of cefuroxime results from inhibition of bacterial cell wall synthesis by binding to essential target proteins in bacterial cytoplasmic membranes. Cefuroxime has bactericidal activity against a wide range of bacterial organisms, including beta-lactamase producing strains.

Pharmacokinetics
Cefuroxime axetil is an oral prodrug of cefuroxime. After oral absorption, cefuroxime axetil is hydrolysed in the intestinal mucosa and blood to release cefuroxime into the plasma. Oral absorption is optimal when administered with food. Peak serum levels of cefuroxime occur approximately 2 to 3 hours after oral dosing, when taken with food. Protein binding is approximately 33 % to 50 %. Cefuroxime is not metabolised and is excreted unchanged in the urine by glomerular filtration and tubular secretion. The elimination half-life is between 1 and 1,5 hours after oral dosing. The elimination half-life is prolonged with renal impairment. Serum levels of cefuroxime are reduced by dialysis.

INDICATIONS:
AUROXIME TABLETS is indicated for the treatment of infections caused by susceptible strains of the following organisms in the following infections:
- Pharyngitis and tonsilitis caused by *Streptococcus pyogenes.*
- Otitis media caused by *Streptococcus pneumoniae, Haemophilus influenzae* (ampicillin-sensitive and resistant strains), *Moraxella (Branhamella) catarrhalis* and *Streptococcus pyogenes.*
- Sinusitis caused by *Streptococcus pneumoniae* and *Haemophilus influenzae.*
- Acute and chronic bronchitis caused by *Streptococcus pneumoniae*, *Haemophilus influenzae* (ampicillin-sensitive strains) and *Haemophilus parainfluenzae* (ampicillin-sensitive strains).
- Acute uncomplicated cystitis caused by *Escherichia coli* and *Klebsiella pneumoniae.*
- Lyme disease caused by *Borrelia burgdorferi.*

CONTRA-INDICATIONS:
- Hypersensitivity to cephalosporin antibiotics or to any components of the formulation.
- Hypersensitivity to penicillin and other beta-lactam antibiotics.

WARNINGS AND SPECIAL PRECUATIONS:

AUROXIME TABLETS should be used with caution in patients with:
- A history of gastrointestinal disease, especially ulcerative colitis, regional enteritis or pseudomembranous colitis.
- Renal function impairment – A reduced dose may be required.
- Porphyria: Safety has not been established.

Pseudomembranous colitis may occur. People who develop abdominal or stomach cramps, abdominal tenderness, severe and watery diarrhea (which may be bloody) and fever, should be investigated for this diagnosis. If the diagnosis of pseudomembranous colitis is suspected, **AUROXIME TABLETS** should be stopped immediately and appropriate therapy initiated.

The Jarisch-Herxheimer reaction has been reported following treatment with **AUROXIME TABLETS** for Lyme disease. The reaction is a common and usually self-limiting consequence of antibiotic treatment for Lyme disease.

Prolonged use of **AUROXIME TABLETS** may result in the overgrowth of non-susceptible organisms (e.g. Candida, Enterococci or *Clostridium difficile*).

INTERACTIONS:
Concurrent administration of probenecid increases the area under the mean serum concentration time-curve by 50 %.

Interactions with Laboratory Tests:
It is recommended that either glucose oxidase or hexokinase methods be used to determine blood/plasma glucose levels in patients receiving **AUROXIME TABLETS.**

This medicine may give false-negative test results with ferricyanide blood glucose test. **AUROXIME TABLETS** does not interfere in the alkaline picrate assay for creatinine.

A false-positive Coombs reaction may appear in patients who receive large doses of **AUROXIME TABLETS.**

PREGNANCY AND LACTATION:
Safety and efficacy in pregnancy and lactation have not been established.

DOSAGE AND DIRECTIONS FOR USE:

Adults:

Sinusitis and acute or chronic bronchitis:
250 mg twice daily for seven days (range 5-10 days)

Acute, uncomplicated cystitis:
125 mg twice daily for seven days (range 5-10 days)

Lyme disease:
Adults and children over 12 years of age: 500 mg twice daily for 20 days

Children:
There is no experience with **AUROXIME TABLETS** in children under 3 months of age.
- 3 months to 2 years of age: 125 mg twice daily
- Over 2 years of age: 250 mg twice daily

AUROXIME TABLETS should be taken half an hour after food for optimum absorption.

SIDE EFFECTS:

Blood and the lymphatic system disorders:
Frequent: Eosinophilia.

Nervous system disorders:
The following side effects have been reported and frequencies are unknown: Headache.

Gastrointestinal disorders:
Less frequent: Nausea, vomiting, abdominal pain, diarrhoea, in some cases accompanied by blood in stools, which may be a symptom of enterocolitis. A particular form of enterocolitis is pseudomembranous colitis (see "**WARNINGS AND SPECIAL PRECAUTIONS**").

Reproductive system and breast disorders:
The following side effects have been reported and frequencies are unknown: Vaginal candidiasis.

Investigations:
The following side effects have been reported and frequencies are unknown: Transient increase in hepatic enzyme levels.

Skin and subcutaneous tissue disorders:
Less frequent: Erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis.

Immune system disorders:
Less frequent: Hypersensitivity reactions including skin rashes, urticaria, pruritus, bronchospasm, drug fever, serum sickness, anaphylaxis.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
(See "**SIDE EFFECTS**")

Symptoms of overdose:
Seizures have been reported.

Treatment of overdose:
Treatment is symptomatic and supportive. Serum levels of **AUROXIME TABLETS** can be reduced by haemodialysis or peritoneal dialysis.

IDENTIFICATION:
AUROXIME TABLETS 125 mg: White to off-white, film-coated capsule shaped tablets with 'A32' debossed on one side and plain on the other side.
AUROXIME TABLETS 250 mg: White to off-white, film-coated capsule shaped tablets with 'A33' debossed on one side and plain on the other side.
AUROXIME TABLETS 500 mg: White to off-white, film-coated capsule shaped tablets with 'A34' debossed on one side and plain on the other side.

PRESENTATION:
AUROXIME TABLETS 125 mg/ 250 mg/ 500 mg
1. PVC/ACLAR-ALUMINIUM
Tablets are packed in 250 micron clear PVC film laminated with 23 micron Aclar as the forming material and aluminium foil 25 microns as the lidding material.

2. ALU-ALU PACK:
Tablets are packed in cold form laminate: 25 micron polyamide / 45 micron aluminium foil / 60 micron PVC film as the forming material and aluminium foil 25 microns as the lidding material.

Pack size: 10s- Each blister contains 10 tablets.

STORAGE INSTRUCTIONS:
Store at or below 30 °C. Do not remove from blister until required for use.
KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER:
SOUTH AFRICA:
AUROXIME TABLETS 125 mg: A40/20.1.1/0725
AUROXIME TABLETS 250 mg: A40/20.1.1/0720
AUROXIME TABLETS 500 mg: A40/20.1.1/0721

NAMIBIA:
AUROXIME TABLETS 125 mg: 08/2.1.1/0013
AUROXIME TABLETS 250 mg: 08/2.1.1/0014
AUROXIME TABLETS 500 mg: 08/2.1.1/0015

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Aurogen South Africa (Pty) Ltd
Woodhill Office Park, Building 1, First Floor
53 Phillip Engelbrecht Avenue
Meyersdal, Ext. 12
1448
Johannesburg
South Africa

DATE OF PUBLICATION OF THE PACKAGE INSERT:
Date of registration:
5 October 2007

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18 September 2021

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DETACH BEFORE DISPENSING

SOUTH AFRICA: S4

NAMIBIA: NS2

AUROXIME TABLETS 125 mg (tablet)
AUROXIME TABLETS 250 mg (tablet)
AUROXIME TABLETS 500 mg (tablet)
Cefuroxime axetil

Read all of this leaflet carefully before you start taking AUROXIME TABLETS
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **AUROXIME TABLETS** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT AUROXIME TABLETS CONTAIN

The active substance is cefuroxime axetil.
AUROXIME TABLETS 125 mg: Each tablet contains cefuroxime axetil (amorphous) equivalent to 125 mg cefuroxime. Sugar free.
AUROXIME TABLETS 250 mg: Each tablet contains cefuroxime axetil (amorphous) equivalent to 250 mg cefuroxime. Sugar free.
AUROXIME TABLETS 500 mg: Each tablet contains cefuroxime axetil (amorphous) equivalent to 500 mg cefuroxime. Sugar free.

The other ingredients are cellulose microcrystalline, croscarmellose sodium, hydrogenated vegetable oil, silica colloidal anhydrous and sodium lauril sulfate.

2. WHAT AUROXIME TABLETS ARE USED FOR

AUROXIME TABLETS are used to treat the following:
- Pharyngitis and tonsilitis caused by *Streptococcus pyogenes.*
- Otitis media caused by *Streptococcus pneumoniae, Haemophilus influenzae* (ampicillin-sensitive and resistant strains), *Moraxella (Branhamella) catarrhalis* and *Streptococcus pyogenes.*
- Sinusitis caused by *Streptococcus pneumoniae* and *Haemophilus influenzae.*
- Acute and chronic bronchitis caused by *Streptococcus pneumoniae*, *Haemophilus influenzae* (ampicillin-sensitive strains) and *Haemophilus parainfluenzae* (ampicillin-sensitive strains).
- Acute uncomplicated cystitis caused by *Escherichia coli* and *Klebsiella pneumoniae.*
- Lyme disease caused by *Borrelia burgdorferi.*

3. BEFORE YOU TAKE AUROXIME TABLETS

Do not take AUROXIME TABLETS:
- if you are hypersensitive (allergic) to cefuroxime axetil or any of the other ingredients of **AUROXIME TABLETS.**
- if you are hypersensitive (allergic) to penicillin and other beta-lactam antibiotics.

Take special care with AUROXIME TABLETS:
- If you have a history of gastrointestinal disease, especially ulcerative colitis, regional enteritis or pseudomembranous colitis.
- If you have kidney problems.
- If you have porphyria: safety has not been established.
- Pseudomembranous colitis may occur. People who develop abdominal or stomach cramps, abdominal tenderness, severe and watery diarrhea (which may be bloody) and fever, should be investigated for this diagnosis. If the diagnosis of pseudomembranous colitis is suspected, **AUROXIME TABLETS** should be stopped immediately and appropriate therapy initiated.
- Tell your doctor if you have syphilis, since a reaction called the "Jarisch-Herxheimer reaction" may occur shortly after starting treatment with **AUROXIME TABLETS.** Symptoms of this reaction include fever, chills and headaches.

Driving and using machinery:
The ability to drive a motor vehicle or operate machinery may be impaired by **AUROXIME TABLETS.** This applies particularly in combination with alcohol.

Taking AUROXIME TABLETS with food and drink:
Take **AUROXIME TABLETS** half an hour after food.

Pregnancy and Breastfeeding
Tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding.
Safety during pregnancy and lactation has not been established.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

Taking other medicines with AUROXIME TABLETS:
AUROXIME TABLETS interacts with probenecid.

Probenecid reduces the renal clearance of cefuroxime.

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

4. HOW TO TAKE AUROXIME TABLETS

Always take **AUROXIME TABLETS** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **AUROXIME TABLETS** is too strong or too weak, talk to your doctor or pharmacist.

Your doctor will prescribe an appropriate dose for you according to your condition.

If you take more AUROXIME TABLETS than you should:
Symptoms of overdose may include: seizures, severe abdominal cramps and vomiting.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control center.

If you forget to take AUROXIME TABLETS:
If you forget to take a dose of your medicine, take it as soon as you remember, and then continue as before. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

5. POSSIBLE SIDE EFFECTS

AUROXIME TABLETS can have side effects.
If any of the following happens, stop taking **AUROXIME TABLETS** and tell your doctor. Immediately go to the casualty department of your nearest hospital:
- Anaphylaxis characterised by: Skin rash, hives, difficulty breathing, swelling of your face, lips, tongue, or throat and / or shock.
- Pseudomembranous colitis (abdominal cramps, watery, severe diarrhoea, fever).

Tell your doctor if you notice any of the following side effects:
- dizziness
- hyperactivity
- headache
- nervousness
- lack of or trouble sleeping
- confusion
- drowsy or sleepiness
- nausea
- vomiting, diarrhoea, abdominal pain

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF AUROXIME TABLETS

Store all medicines out of the reach and sight of children.

Store at or below 30 °C. Do not remove from blister until required for use.

Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF AUROXIME TABLETS

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2. ALU-ALU PACK:
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8. IDENTIFICATION OF AUROXIME TABLETS

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9. REGISTRATION NUMBER/REFERENCE NUMBER

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10. NAME AND ADDRESS OF REGISTRATION HOLDER

Aurogen South Africa (Pty) Ltd
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53 Phillip Engelbrecht Avenue
Meyersdal, Ext. 12
1448
Johannesburg
South Africa

11. DATE OF PUBLICATION
Date of registration:
5 October 2007

Date of revision:
18 September 2021