SCHEDULING STATUS: S4

PROPRIETARY NAME AND DOSAGE FORM:
AMOXYCILLIN 250 OETHMAAN Capsules

COMPOSITION:
Each AMOXYCILLIN 250 OETHMAAN Capsule contains: amoxycillin trihydrate equivalent to 250 mg amoxycillin.
Other excipients: magnesium stearate, microcrystalline cellulose and hard gelatine capsule shell
Sugar free.

PHARMACOLOGICAL CLASSIFICATION:
A 20.1.2 Penicillins

PHARMACOLOGICAL ACTION:
Amoxycillin is a penicillinase-susceptible penicillin and exhibits *in vitro* bacterial activity (*in vitro* sensitivity does not necessary imply *in vivo* efficacy) against strains of Gram-negative and Gram-positive organisms, including:

Gram-positive bacteria:	Gram-negative bacteria:
Staphylococcus aureus (penicillin-sensitive)*	Neisseria gonorrhoeae*
Streptococcus pyogenes	Neisseria meningitidis
Streptococcus viridans*	Haemophilus influenzae**
Streptococcus faecalis*	Bordetella pertussis
Diplococcus pneumoniae*	Escherichia coli*
Corynebacterium species*	Salmonella typhi
Clostridium species*	Salmonella species
Bacillus anthracis*	Shigella species
	Brucella species
	Proteus mirabilis

* Sensitivity tests must be performed as increasing strains of these organisms show resistance.
** Except type B-strains causing meningitis in children.

INDICATIONS:
- Upper respiratory tract infections
- Lower respiratory tract Infections
- Otitis media
- Typhoid fever
- Upper urinary tract infections
- Lower urinary tract infections
- Skin and soft tissue infections
- Gonorrhoea
- Gastrointestinal tract infections
- Non-specific urethritis

CONTRAINDICATIONS:
Hypersensitivity to amoxycillin or to any of the ingredients in AMOXYCILLIN 250 OETHMAAN capsules.
Sensitivity to penicillins or any of the cephalosporins. Cases of cross sensitivity have been reported.
AMOXYCILLIN 250 OETHMAAN is contraindicated in babies born of hypersensitive mothers in the neonatal period.

WARNINGS AND SPECIAL PRECAUTIONS
When administered to a patient with penicillin sensitivity, anaphylactic shock may occur. Adrenaline, corticosteroids and antihistamines should be used to treat anaphylaxis.

Patients known to be sensitive to penicillin should be given an antibiotic of another class. Sensitised patients may also react to the cephalosporins and other beta-lactam antibiotics. Penicillin should be given with caution to patients with a history of allergy, especially to these medicines.

INTERACTIONS:
Broad spectrum antibacterial agents have been reported to decrease oral contraceptive efficacy.
Absorption of other medicines may be affected due to AMOXYCILLIN 250 OETHMAAN's effect on the gastrointestinal flora.
The possibility of prolonged bleeding time following oral treatment with a broad spectrum antibiotic such as AMOXYCILLIN 250 OETHMAAN should be borne in mind in patients receiving anticoagulants.
There may be antagonism between AMOXYCILLIN 250 OETHMAAN, a bactericidal agent, and bacteriostatic agents such as chloramphenicol.
In vitro incompatibility with other medicines may occur, e.g. aminoglycosides may be inactivated.
An increased frequency of skin rashes has been reported in patients receiving AMOXYCILLIN 250 OETHMAAN with allopurinol.

PREGNANCY AND HUMAN REPRODUCTION
The safety in pregnancy and lactation has not been established.
AMOXYCILLIN 250 OETHMAAN is contraindicated in babies born of hypersensitive mothers in the neonatal period.

DOSAGE AND DIRECTIONS FOR USE:
The average adult dose for AMOXYCILLIN 250 OETHMAAN is 750 mg to 1.5 g per day given in three divided doses, one hour before or two hours after food.

Specific dosage:
Acute typhoid fever: 1000 mg every six hours for 14 days.
Gonorrhoea: 2 to 3 g stat (immediately) in conjunction with probenecid.

SIDE-EFFECTS:
Gastrointestinal effects like diarrhoea and nausea are the most common adverse effects. A sore mouth or tongue or a black hairy tongue have occasionally been reported.
Hypersensitivity reactions especially skin rashes. Immediate reactions include anaphylaxis which is sometimes fatal, angioedema, urticaria, and some maculopapular rashes. Late reactions may include serum sickness like reactions, haemolytic anaemia, and acute interstitial nephritis.
Neutropenia. Warning signs include fever, rash and eosinophilia. Monitoring of leukocyte count is recommended during long-term treatment with high doses.

Eosinophilia.
Hepatitis and cholestatic jaundice have been reported infrequently.

Some patients with syphilis may experience a Jarisch-Herxheimer reaction shortly after starting treatment with penicillin. Symptoms include fever, chills, headache and reactions at the site of the lesions. The reaction can be dangerous in cardiovascular syphilis, or where there is a serious risk of increased local damage such as with optic atrophy.
Pseudomembraneous colitis has been associated with the use of AMOXYCILLIN 250 OETHMAAN.
Erythema multiforme (including Stevens-Johnson syndrome), toxic epidermal necrolysis, and exfoliative dermatitis.
Care is necessary if very high doses of penicillin are given, especially if renal function is poor, because of the risk of neurotoxicity. Renal and haematological status should be monitored during prolonged and high-dose therapy. Care should also be taken in congestive heart failure.
Penicillin therapy changes the normal bacterial flora and can lead to supra-infection with penicillin resistant organisms including Pseudomonas or Candida, particularly with prolonged use.
It should preferably not be given to patients with infectious mononucleosis since they are especially susceptible to AMOXYCILLIN 250 OETHMAAN induced skin rashes. Patients with lymphatic leukemia or possibly HIV infection may also be at risk of developing skin rashes.
Doses should be reduced in severe renal failure.
Caution must be exercised in treating patients with dehydration or oliguria because of the possibility of crystaluria.
Increase in liver enzymes.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
(See "SIDE-EFFECTS and WARNINGS AND SPECIAL PRECAUTIONS").
Treatment is symptomatic and supportive.
Anaphylactic reactions may be treated with adrenaline, corticosteroids and antihistamines.

IDENTIFICATION:
Opaque, yellow, size 2 capsule containing a white to cream coloured powder.

PRESENTATIONS:
Amber glass bottles, securitainers, patient ready packs or blister packs of 15, 100, 500 or 1000 capsules.

STORAGE INSTRUCTIONS:
Store tightly closed in a dry place at or below 25 °C and protect from light.
KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER:
AMOXYCILLIN 250 OETHMAAN : 27/20.1.2/0577

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Oethmaan Biosims (PTY) Ltd.
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SKEDULERINGSTATUS: S4

EIENDOMSNAAM EN DOSEERVORM
AMOXYCILLIN 250 OETHMAAN kapsules

SAMESTELLING
Elke AMOXYCILLIN 250 OETHMAAN-tablet bevat amoksisilliëntrihidraat gelykstaande aan 250 mg amoksisillien.
Ander bestanddele: magnesiumstearaat, mikrokristallyne sellulose en kapsuledop van harde gelatien
Suikervry

FARMAKOLOGIESE KLASSIFIKASIE
A 20.1.2 Penisilliene

FARMAKOLOGIESE WERKING
Amoksisillien is 'n penisillien wat vatbaar is vir penisillinase en *in vitro* vertoon dit antibakteriële aktiwiteit (*in vitro*-sensitiwiteit impliseer nie noodwendig *in vivo*-effektiwiteit nie) teen stamme van gram-negatiewe en gram-positiewe organismes, waaronder:

Gram-positiewe bakterieë:	Gram-negatiewe bakterieë:
Staphylococcus aureus (penisilliensensitief)*	Neisseria gonorrhoeae*
Streptococcus pyogenes	Neisseria meningitidis
Streptococcus viridans*	Haemophilus influenzae**
Streptococcus faecalis*	Bordetella pertussis
Diplococcus pneumoniae*	Escherichia coli*
Corynebacterium spesies*	Salmonella typhi
Clostridium spesies *	Salmonella spesies
Bacillus anthracis*	Shigella spesies*
	Brucella spesies
	Proteus mirabilis

* Sensitiwiteitstoetse moet gedoen word omdat al meer stamme van hierdie organismes weerstand toon.
** Behalwe tipe B-stamme wat meningitis in kinders veroorsaak.

INDIKASIES
- Boonstelugweginfeksies
- Laer lugweginfeksies
- Otitis media
- Ingewandskoors
- Boonste urineweginfeksie
- Onderste urienweginfeksie
- Infeksies van die vel en sagte weefsel
- Gonorree
- Gastro-intestinale weg infeksies
- Nie-spesifieke uretritis

KONTRA-INDIKASIES
Hipersensitiwiteit vir amoksisillien of enige van die bestanddele van AMOXYCILLIN 250 OETHMAAN-kapsules
Sensitiwiteit vir penisilliene of enige van die kefalosporiene. Gevalle van kruissensitiwiteit is aangemeld.
AMOXYCILLIN 250 OETHMAAN is in die neonatale periode teenaangedui vir babas gebore van hipersensitiewe moeders.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREëLS
As dit gegee word aan 'n pasiënt met sensitiwiteit vir penisillien, kan anafilaktiese skok voorkom. Adrenalien, kortikosteroïede en histamiene moet gebruik word om anafilakse te behandel.
Pasiënte wat sensitief is vir penisillien, moet 'n antibiotikum van 'n ander klas kry. Gesensitiseerde pasiënte kan ook op die kefalosporiene en ander beta-laktaamantibiotika reageer. Penisillien moet versigtig gegee word aan pasiënte met 'n geskiedenis van allergie, veral vir medisyne.

INTERAKSIES
Dit is gemeld dat breëspektrum antibakteriese middels die effektiwiteit van orale voorbehoedmiddels verminder.
Absorpsie van ander medisyne kan as gevolg van AMOXYCILLIN 250 OETHMAAN se effek op die gastro-intestinale flora beïnvloed word.
Die moontlikheid van langdurige bloedingstyd na orale behandeling met 'n breëspektrumantibiotikum soos AMOXYCILLIN 250 OETHMAAN moet in gedagte gehou word vir pasiënte wat antistolmiddels ontvang.
Daar kan antagonisme wees tussen AMOXYCILLIN 250 OETHMAAN, 'n bakteriedodende middel en bakteriostatiese middels soos chlooramfenikol. *In vitro* kan onverenigbaarheid met ander medisyne voorkom, aminoglikosiede kan byvoorbeeld geïnaktiveer word.
'n Hoër frekwensie van veluitslag is aangemeld in pasiënte wat AMOXYCILLIN 250 OETHMAAN saam met allopurinol gekry het.

SWANGERSKAP EN MENSLIKE VOORTPLANTING
Veiligheid en effektiwiteit tydens swangerskap en borsvoeding is nie bepaal nie.
AMOXYCILLIN 250 OETHMAAN is in die neonatale periode teenaangedui vir babas gebore van hipersensitiewe moeders.

DOSIS EN GEBRUIKSAANWYSINGS
Die gemiddelde volwasse dosis van AMOXYCILLIN 250 OETHMAAN is 750 mg tot 1,5 g per dag wat in drie verdeelde dosisse, een uur voor of twee uur na voedsel, gegee word.

Spesifieke dosis:
Akute ingewandskoors: 1000 mg elke ses uur vir 14 dae.
Gonorree: 2 tot 3 g stat (onmiddellik) saam met probenesied.

NEWE-EFFEKTE
Gastro-intestinale effekte soos diarree en naarheid is die mees algemene nadelige effekte. 'n Seer mond of tong of swart harige tong is soms aangemeld.
Hipersensitiwiteitsreaksies en veral veluitslag. Onmiddellike reaksies is onder meer anafilakse, wat soms noodlottig is, angioedeem, urtikarie en sekere makulopapulêre uitslag. Laat reaksies kan serumsiekte insluit soos reaksies, hemolitiese anemie en akute interstisiële nefritis.
Neutropenie. Die waarskuwingstekens is onder meer koors, veluitslag en eosinofilie. Monitering van leukosiettelling tydens langtermynbehandeling met hoë dosisse word aanbeveel.
Eosinofilie.
Hepatitis en cholestatiese geelsug is soms aangemeld.
Sommige pasiënte met sifilis kan kort ná die behandeling met penisillien 'n Jarisch-Herxheimer-reaksie ervaar. Simptome is onder meer koors, kouekoors, hoofpyn en reaksies by die plek van die letsel. Met kardiovaskulêre sifilis of as daar 'n erge risiko vir groter lokale skade is soos met optiese atrofie kan die reaksie gevaarlik wees.
Pseudomembraankolitis het met die gebruik van AMOXYCILLIN 250 OETHMAAN voorgekom.
Multivorme eriteem (waaronder Stevens-Johnsonsindroom), toksiese epidermale nekrolise en afskilferende dermatitis.
Wees as gevolg van die risiko van neurotoksisiteit versigtig as baie hoë dosisse penisillien gegee word, veral as die nierfunksie swak is. Nier- en hematologiese status moet tydens langdurige behandeling en met hoë dosisse gemonitor word. Wees ook versigtig met kongestiewe hartversaking.
Behandeling met penisilline verander die normale bakteriële flora en kan veral met langdurige gebruik tot superinfeksies deur organismes weerstandig teenoor penisillien, waaronder pseudomonas of kandida, lei.
Dit moet verkieslik nie gegee word aan pasiënte met infektiewe mononukleose nie, omdat hulle besonder vatbaar is vir veluitslag geïnduseer deur AMOXYCILLIN 250 OETHMAAN. Pasiënte met limfatiese leukemie of moontlik MIV-infeksie kan ook 'n risiko hê om veluitslag te ontwikkel.
Met ernstige nierversaking moet dosisse verlaag word.
Wees versigtig met die behandeling van pasiënte met dehidrasie of oligurie vanweë die moontlikheid vir kristalurie.
Styging in lewerensiemvlakke.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN
Kyk "NEWE EFFEKTE" en "WAARSKUWINGS en SPESIALE VOORSORGMAATREëLS".
Behandeling is simptomaties en ondersteunend.
Anafilaktiese reaksies kan met adrenalien, kortikosteroïede en antihistamiene behandel word.

IDENTIFIKASIE
Ondeursigtige, geel, grootte 2-kapsule wat 'n wit tot roomkleurige poeier bevat.

AANBIEDINGS
Amber glasbottels, sekuriteitshouers, pasiëntregpakke of stulpverpakkings met 15, 100, 500 of 1000 kapsules.

BEWARINGSINSTRUKSIES
Bêre dig geslote op 'n droë plek by of onder 25 °C en beskerm teen lig.
HOU BUITE DIE BEREIK VAN KINDERS.

REGISTRASIENOMMER
AMOXYCILLIN 250 OETHMAAN: 27/20.1.2/0577

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