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
- Infections of the lower urinary tract:
- 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[1] 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:	1 000 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.

Pseudomembranous 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.

PRESENTATION:

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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