Patient Information Leaflet

Scheduling Status: Schedule 4

Proprietary name, Strength and Pharmaceutical Form:

AMOXYCILLIN 250 OETHMAAN CAPSULES (each capsules contains AMOXYCILLIN trihydrate equivalent to amoxycillin 250 mg.)

Please read this leaflet carefully before taking AMOXYCILLIN 250 OETHMAAN CAPSULES.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine 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 AMOXYCILLIN 250 OETHMAAN CAPSULES CONTAIN

Active ingredients: AMOXYCILLIN trihydrate equivalent to AMOXYCILLIN 250 mg.

Inactive ingredients: Magnesium stearate, microcrystalline cellulose and hard gelatine capules shell (size 2).

AMOXYCILLIN 250 OETHMAAN CAPULES are sugar free.

2. WHAT AMOXYCILLIN 250 OETHMAAN IS USED FOR

AMOXYCILLIN 250 OETHMAAN contains AMOXYCILLIN which is a broad spectrum antibiotic known as penicillin.

AMOXYCILLIN 250 OETHMAAN is used in the treatment of:

- Mild to moderate infections:
    - Of the ear, throat, nose and sinuses.
    - Chest infections such as bronchitis and pneumonia.
    - Stomach infections such as typhoid fever.
    - Early Lyme disease (from a tick bite)

- Infections where there is proof that the organism causing the infection is sensitive to AMOXYCILLIN:
- Skin and soft tissue infections.
- Urinary tract infections
- To prevent endocarditis.
- Stomach ulcers caused by the bacterium *Helicobacter pylori*

3. BEFORE YOU TAKE AMOXYCILLIN 250 OETHMAAN

Do not take AMOXYCILLIN 250 OETHMAAN:

If you are hypersensitive (allergic) to penicillins or to cephalosporins or any of the other ingredients of **AMOXYCILLIN 250 OETHMAAN**. If you are allergic to cephalosporin antibiotic, such as cephalexin and cefuroxime, you may also be allergic to penicillin antibiotics.

Take special care with AMOXYCILLIN 250 OETHMAAN:

Before taking this medication, tell your doctor:

- If you are allergic to anything or if you have a history of penicillin or cephalosporin hypersensitivity. You may experience severe allergic reactions with AMOXYCILLIN 250 OETHMAAN.
- If you have a sore throat with sores in your throat.
- If you have existing medical problems such as severe diarrhoea or other stomach conditions, bleeding disorders, jaundice, liver or kidney problems, syphilis or lymphatic leukaemia.
- If you are pregnant or breast-feeding your baby.

Taking AMOXYCILLIN 250 OETHMAAN with food or drink:

You may take this capsule on a full or empty stomach. If you take it with food, it may decrease the incidence of gastrointestinal side effects such as nausea, vomiting and diarrhoea.

Pregnancy and breastfeeding:

Ask your doctor for advice before taking any medicine

Data on a limited number of exposed pregnancies indicate no adverse effects of AMOXYCILLIN on pregnancy or on the health of the foetus or newborn child. As a precautionary measure, AMOXYCILLIN should only be used during pregnancy if in the judgement of the physician the potential

benefits outweigh the possible hazards.

This medicine passes into breast milk in small quantities; therefore in some cases it may be necessary to breastfeeding.

Driving and using machinery:

This medicine has no known influence on the ability to drive and use machines, but you should refrain from driving or using machinery until you know how this medicine affects you as it may cause nausea, dizziness or headache.

Taking other medicines with AMOXYCILLIN 250 OETHMAAN:

- **AMOXYCILLIN 250 OETHMAAN** may reduce the efficacy of your oral contraceptives, making them less reliable.
- The concomitant administration of allopurinol (used to treat gout) may increases the incidence of skin rashes.
- If you have to test for the presence of glucose in your urine, you may get false positive readings during **AMOXYCILLIN 250 OETHMAAN** treatment.
- Methotrexate: (used to treat arthritis): the toxicity of methotrexate may be increased.
- Digoxin: (used to treat certain heart diseases): the absorption of digoxin may be increased.
- Anticoagulants (to prevent blood clotting) such as warfarin: the tendency to bleed may be increased.

4. HOW TO TAKE AMOXYCILLIN 250 OETHMAAN CAPSULES

Always take **AMOXYCILLIN 250 OETHMAAN** 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 **AMOXYCILLIN 250 OETHMAAN** is too strong or too weak, talk to your doctor or pharmacist.

The usual dose for adults and children over 40 kg bodyweight is 750 mg to 3000 mg daily in two to three divided doses.

For the prevention of heart infections:

In adults, 2000-3000 mg is given in the hour before the surgery.

Your doctor may decide to increase the dosage up to a maximum of 4 g per day depending on your specific condition.

If your kidney function is severely impaired your doctor may reduce your dose.

If you are receiving dialysis the maximum dose is 500 mg per day (two capsules).

If you take more AMOXYCILLIN 250 OETHMAAN than you should:

In the event of overdose you may experience vomiting, nausea and diarrhoea. Consult your doctor or pharmacist, if neither is available, seek help at the nearest hospital or poison control centre. Take this leaflet and the rest of the remaining capsules with you so the doctor will know what you have taken

If you forget to take AMOXYCILLIN 250 OETHMAAN:

Take the missed dose as soon as possible. However, if it is almost time for you next dose, continue to take the next capsule at the usual time. Do not take a double dose.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

5. POSSIBLE SIDE EFFECTS

Like all medicines, **AMOXYCILLIN 250 OETHMAAN** can cause side effects in some patients.

Contact your doctor immediately if you experience any of the following side effects:

These side-effects have been reported frequently:

- Skin rash; hives or itching skin.
- Severe stomach pain or cramps; watery and severe diarrhoea.
- Vaginal itching and discharge.

These side-effects have been reported less frequently:

- Allergic reactions, including fast or irregular breathing, swelling of the face, sudden decrease in blood pressure.
- Sore mouth with white patches on your tongue and/or mouth.
- Fever; joint pain; blistering or peeling skin.
- Yellow eyes or skin.
- Convulsions.

Other side-effects may occur that usually do not need medical attention. These side-effects may go

way during treatment as your body adjust to the medicine.

These side-effects have been reported frequently:

- Headache
- Dizziness
- Tiredness
- Nausea and vomiting
- Hot flushes
- Black ‘hairy’ tongue

These side-effects have been reported less frequently:

- Tooth discolouration (which can be removed by brushing the teeth)

Not all side-effects reported for AMOXYCILLIN 250 OETHMAAN Capsules are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF AMOXYCILLIN 250 OETHMAAN CAPSULES

- Store tightly closed in a dry place below 25ºC. Protect from light.
- Do not store your medicine in the bathroom.
- KEEP ALL MEDICINES OUT OF REACH OF CHILDREN
- Do not use the capsules after the expiry date printed on the carton, label or blister.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF AMOXYCILLIN 250 OETHMAAN

Amber glass bottles, securitainers (plastic container), patient ready packs or blister packs of 15, 100, 500 or 1000 capsules.

8. IDENTIFICATION OF AMOXYCILLIN 250 OETHMAAN

AMOXYCILLIN 250 OETHMAAN: Opaque, yellow, size 2 capsule containing a white to cream coloured powder.

9. REGISTRATION NUMBER

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Oethmaan Biosims (Pty) Ltd

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11. DATE OF PUBLICATION

25 April 2000