APPROVED PATIENT INFORMATION LEAFLET

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AURO AMOXICLAV 375 mg (Tablet)

AURO AMOXICLAV 625 mg (Tablet)

AURO AMOXICLAV 1000 mg (Tablet)

Amoxicillin and Clavulanic acid

Read all of this leaflet carefully before you start taking this medicine.

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

This medicine has been prescribed for you personally arsd you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT AURO AMOXICLAV CONTAINS

The active substances are Amoxicillin and Clavulanic acid.

AURO AMOXICLAV 375 mg:

Each film-coated tablet contains amoxicillin trihydrate equivalent to 250 mg amoxicillin, and potassium clavulanate equivalent to 125 mg clavulanic acid.

AURO AMOXICLAV 625 mg:

Each film-coated tablet contains amoxicillin trihydrate equivalent to 500 mg amoxicillin, and potassium clavulanate equivalent to 125 mg clavulanic acid.

AURO AMOXICLAV 1000 mg:

Each film-coated tablet contains amoxicillin trihydrate equivalent to 875 mg amoxicillin, and potassium clavulanate equivalent to 125 mg clavulanic acid.

The other ingredients are cellulose microcrystalline, lsopropyl alcohol, magnesium stearate, methylene chloride, opadry white, silica colloidal anhydrous, sodium starch glycolate, silica colloidal anhydrous.

2. WHAT AURO AMOXICLAV IS USED FOR

AURO AMOXICLAV formulations are indicated for the treatment of infections caused by amoxicillin resistant organisms producing beta-lactamases sensitive to clavulanic acid:

Upper respiratory tract infections, such as sinusitis, recurrent otitis media, tonsillitis.

Lower respiratory tract infections, such as bronchitis and bronchopneumonia

Genito-urinary tract infections, such as cystitis, urethritis, pyelonephritis.

Skin and soft tissue infections.

AURO AMOXICLAV formulations will also be effective in the treatment of infections caused by amoxicillin sensitive organisms at the appropriate amoxicillin dosage since in this situation the clavulanic acid component does not contribute to the therapeutic effect.

3. BEFORE YOU TAKE AURO AMOXICLAV

Do not take AURO AMOXICLAV:

- If you are hypersensitive (allergic) to penicillins or cephalosporins, or any of the ingredients of **AURO AMOXICLAV**.
- If you have a previous history of amoxicillin/clavulanic-associated liver dysfunction.

Take special care with AURO AMOXICLAV:

- If an allergic reaction occurs, **AURO AMOXICLAV** should be discontinued and the appropriate therapy instituted.
- **AURO AMOXICLAV** should **be** avoided if infectious mononucleosis is suspected.
- Periodic assessment of organ function, including renal, hepatic and haematopoietic functions, is advisable during prolonged therapy.
- If you suffer from kidney or liver disease.
- If you have syphilis.
- When high doses are administered, adequate fluid intake and urinary output must be maintained.
- The sodium content must be taken into account in patients on a sodium-restricted diet if the administration of high doses is necessary.
- Periodic assessment of organ system functions, including renal, hepatic and haematopoietic function, is advisable during prolonged therapy. Since **AURO AMOXICLAV** contains amoxicillin,

an aminopenicillin, it is not the treatment of choice in patients presenting with sore throat or pharyngitis because of the possibility that the underlying cause is infectious mononucleosis, in the presence of which there is a high incidence of rash if amoxicillin is used. **AURO AMOXICLAV** should be given with caution to patients with lymphatic leukemia since they are especially susceptible to amoxicillin induced skin rashes.

Pregnancy and Breast-feeding*:*

Use in Pregnancy:

The safety of **AURO AMOXICLAV** in pregnancy has not been established.

Use in Lactation:

Amoxicillin is distributed into breast milk. Although significant problems in humans have not been documented, the use of amoxicillin by nursing mothers may lead to sensitisation, diarrhoea, candidiasis and skin rash in the infant.

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

Taking other medicines with AURO AMOXICLAV:

AURO AMOXICLAV interacts with probenecid, oral contraceptives, tetracyclines.

It is recommended that when testing for the presence of glucose in urine during **AURO AMOXICLAV** treatment, enzymatic glucose oxidase methods should be used. Due to the high urinary concentrations of amoxicillin, false positive readings are common with chemical methods.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **AURO AMOXICLAV** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

4. HOW TO TAKE AURO AMOXICLAV

Always take **AURO AMOXICLAV** 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 **AURO AMOXICLAV** is too strong or too weak, talk to your doctor or pharmacist.

For Oral Formulations:

Tablets should be taken immediately before a meal.

Dosage:

General information: For infections caused by amoxicillin sensitive organisms the dosage is that approved for amoxicillin as the clavulanic acid component does not contribute to the therapeutic effect.

Adults:

The adult dose of **AURO AMOXICLAV** is one **AURO AMOXICLAV 375 mg** tablet every eight hours at the start of a meal. For more severe infections and infection of the respiratory tract, the dose should be one **AURO AMOXLCLAV 625 mg** tablet every eight hours at the start of a meal, or one **AURO AMOXICLAV 1000 mg** tablet every **12** hours at the start of a meal.

Since **AURO AMOXICLAV 375 mg, 625 mg and 1000 mg** tablets contain the same amount of clavulanic acid (125 mg as the potassium salt) two **AURO AMOXICLAV 325 mg** tablets are not equivalent to one **AURO AMOXICLAV 625 mg** tablet, and two **AURO AMOXICLAV 625 mg** tablets are not equivalent to one **AURO AMOXICLAV 1000 mg.** Therefore, two **AURO AMOXICLAV 375 mg** tablets should not be substituted for one **AURO AMOXICLAV 625 mg** tablet or two **AURO AMOXICLAV 625 mg** tablets for one **AURO AMOXICLAV 1000 mg** tablet for the treatment of more severe infections.

Impaired renal function:

Both amoxicillin and clavulanic acid are excreted by the kidneys and the serum half-life of each increases in patients with renal failure. Therefore, the dose may need to be reduced or the interval extended.

Dosage adjustments are based on the maximum recommended level of amoxicillin. The following schedule is proposed:

AURO AMOXICLAV 375 mg, 625 mg:

Mild impairment (creatinine clearance greater than 30 ml/minute): no change in dosage.

Moderate impairment (creatinine clearance 10 to 30 30 ml/minute): 1 tablet every 12 hours.

Severe impairment (creatinine clearance less than 10 30 ml/minute): half a tablet every 12 hours.

AURO AMOXICLAV 1000 mg should not be used in patients with glomerular filtration rate of less than 30 ml/minute.

Haemodialysis decreases serum concentrations of both amoxicillin and clavualnic acid and an additional dose should be administered at the end of dialysis.

Dosage Guide:

Amoxicillin-Sensitive Organisms

Product	**Upper Respiratory Tract Infection**	**Lower Respiratory Tract Infection**	**Urinary Tract Infection**	**Skin and Soft Tissue Infection**
AURO AMOXICLAV 375 mg	1 Tablet 8 hourly	-	1 Tablet 8 hourly	1 Tablet 8 hourly
AURO AMOXICLAV 625 mg	1 Tablet 8 hourly	1 Tablet 8 hourly	1 Tablet 8 hourly	1 Tablet 8 hourly
AURO AMOXICLAV 1000 mg	1 Tablet 12 hourly	1 Tablet 12 hourly	1 Tablet 12 hourly	1 Tablet 12 hourly

Amoxicillin-Resistant Organisms

Product	**Upper Respiratory Tract Infection**	**Lower Respiratory Tract Infection**	**Urinary Tract Infection**	**Skin and Soft Tissue Infection**

AURO AMOXICLAV 375 mg	-	-	1 Tablet 8 hourly	1 Tablet 8 hourly
AURO AMOXICLAV 625 mg	1 Tablet 8 hourly	1 Tablet 8 hourly	1 Tablet 8 hourly	1 Tablet 8 hourly
AURO AMOXICLAV 1000 mg	1 Tablet 12 hourly	1 Tablet 12 hourly	1 Tablet 12 hourly	1 Tablet 12 hourly

Children:

The dose of **AURO AMOXICLAV** in children is 25-50 mg/kg/day of the 4 parts amoxicillin, 1 part clavulanic acid preparations (which corresponds to a daily dosage of the equivalent of 20 - 40 mg/kg of amoxicillin and 5 - 10 mg/kg of clavulanic acid) to be taken in divided doses every eight hours, at the start of a meal.

If you take more AURO AMOXICLAV than you should:

Overdosage with amoxicillin is usually asymptomatic. However, gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and symptoms of water and electrolyte imbalance should be treated symptomatically.

Adequate fluid intake and urinary output must be maintained to minimise the possibility of crystalluria. Amoxicillin may be removed from the circulation by haemodialysis. The molecular weight, degree of protein binding and pharmacokinetic profile of clavulanic acid together with information from a single patient with renal insufficiency all suggest that this compound may also be removed by haemodialysis.

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

If you forget to take AURO AMOXICLAV:

Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

AURO AMOXICLAV can have side effects.

The most frequently reported adverse effects are diarrhoea, nausea, vomiting, indigestion, abdominal pain, skin rashes, urticaria and erythema multiforme, vaginitis, abnormal taste, headache, dizziness, tiredness and hot flushes.

The incidence and severity of adverse effects, particularly nausea and diarrhoea, increased with the higher recommended dose and can be minimised by administering **AURO AMOXICLAV** at: the start of a meal. In addition, as these symptoms are especially related to the potassium clavulanate component, where these gastrointestinal symptoms occur and a higher concentration of amoxicillin is required, consideration should be given to administering the additional amoxicillin separately.

The following adverse reactions have been reported and may occur with **AURO AMOXICLAV:**

Hypersensitivity reactions:

Skin rashes, pruritus and urticaria, serum sickness-like syndrome, erythema multiforme, rare cases of Stevens-Johnson syndrome, hypersensitivity vasculitis and less frequently bullous exfoliative dermatitis and toxic epidermal nercrolysis have been reported. Whenever such reactions occur, **AURO AMOXICLAV** should be discontinued. Serious and occasional fatal hypersensitivity (anaphylactic) reactions and angioneurotic oedema can occur with oral penicillin**.**

Interstitial nephritis can occur rarely.

Gastrointestinal reactions:

Nausea, vomiting, diarrhoea, gastritis, stomatitis, glossitis, black 'hairy' tongue, enterocolitis, mucocutaneous candidiasis and antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis). If gastro-intestinal reactions are evident, they may be reduced by taking **AURO AMOXICLAV** at the start of a meal.

Hepatic effects:

Hepatitis and cholestatic jaundice have been reported. The events may be severe, and occur predominantly in adults or elderly patients. Signs and symptoms usually occur during or shortly after treatment, but in some cases may not become apparent until several weeks after treatment has

ceased.

The hepatic effects are usually reversible. However, in extremely rare circumstances, death has been reported. These have almost always been cases associated with serious underlying disease or concomitant medication.

A moderate raise in Aspartate transaminase (AST) and/or Alanine transaminase (ALT) has been noted in patients treated with **AURO AMOXICLAV,** but the significance of these findings is unknown.

Renal effects:

Crystalluria has been reported

Haematological effects:

Haemolytic anaemia, reversible thrombocytopenia, thrombocytopenic purpura, eosinophilia, reversible leucopenia and agranulocytosis have been reported. These reactions are usually reversible on discontinuation of therapy **and** are believed to be hypersensitivity phenomena. A slight thrombocytosis was noted in less than 1% of the patients treated with **AURO AMOXICLAV.** Prolongation of bleeding time and prothrombin time have also been reported less frequently. Appropriate monitoring should be undertaken when anticoagulants are prescribed concomitantly.

CNS Effects:

CNS effects have been seen rarely. These include reversible hyperactivity, dizziness, headache and convulsions. Convulsions may occur with impaired renal function or in those receiving high doses.

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 AURO AMOXICLAV

Store all medicines out of the reach of children.

Store at or below 30 °C**.**

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF AURO AMOXICLAV

AURO AMOXICLAV 375 mg:

Tablets are packed in 25 micron Polyamide /45 micron Aluminium foil / 60 micron PVC film (width 138 mm) as the forming material and 25 micron Printed Aluminium foil (width 138 mm) as the lidding material.

Each blister contains 5 tablets.

Pack size: 15's: Each carton contains 3 blisters of 5 tablets each.

Pack size: 100's: Each carton contains 20 blisters of 5 tablets each.

AURO AMOXICLAV 625 mg:

Tablets are packed in 25 micron Polyamide /45 micron Aluminium foil 160 micron PVC film (width 138 **mm)** as the forming material and 25 micron Printed Aluminium foil (width 138 mm) as the lidding material.

Each blister contains 5 tablets.

Pack size: 15's: Each carton contains 3 blisters of 5 tablets each.

AURO AMOXICLAV 1000 mg:

1. Tablets are packed in 25 micron Polyamide / 45 micron Aluminium foil 160 micron PVC film (width 138 mm) as the forming material and 25 micron Printed Aluminium foil (width 138 mm) as the lidding material.

   Each blister contains 5 tablets.

   Pack size: 10's: Each carfon contains 2 blisters of 5 tablets each.
2. Tablets are packed in printed 40 micron Aluminium foil laminated with 150-gauge poly on one side and plain 40 micron Aluminium foil laminated with 150-gauge poly on other side. Each strip contains 10 tablets.

   Pack size: 10's: One strip pack containing tablets.

8. IDENTIFICATION OF AURO AMOXICLAV

AURO AMOXICLAV 375 mg:

White oval shaped film coated tablets, debossed with 'A' on one side and '63' on the other side

AURO AMOXICLAV 625 mg:

White oval shaped film coated tablets, debossed with 'A' on one side and **'84'** on the other side.

AURO AMOXICLAV 1000 mg:

White coloured, capsule shaped, film coated tablets, debossed with 'A' on one side and with a score line in between **'6'** and '5' on the other side.

9. REGISTRATION NUMBER:

AURO AMOXICLAV 375 mg: 41/20.1.2/0535

AURO AMOXICLAV 625 mg: 41/20.1.2/0536

AURO AMOXICLAV 1 000 mg 41/20.1.2/0537

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Aurogen South Africa (Pty) Ltd

Woodhill Office Park, Building 1, 53 Phillip Engelbrecht Avenue

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Johannesburg, South Africa

11. DATE OF PUBLICATION OF THE PACKAGE INSERT:

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