APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

AURO AMOXICLAV 375 mg (Tablet)

AURO AMOXICLAV 625 mg (Tablet)

AURO AMOXICLAV 1000 mg (Tablet)

Amoxicillin and Clavulanic acid

Sugar free.

Read all of this leaflet carefully before you start taking this AURO AMOXICLAV.

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

If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

AURO AMOXICLAV 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.

What is in this leaflet

1. What AURO AMOXICLAV is and what it is used for

AURO AMOXICLAV is an antibiotic and works by killing bacteria that cause infections. **AURO AMOXICLAV** contains a combination of two medicines (amoxicillin and clavulanic acid) and belongs to a group of medicines called “penicillins”.

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 (inner ear infection), tonsillitis.
- Lower respiratory tract infections, such as bronchitis (acute and chronic infection of the airway) and bronchopneumonia (infection of the lungs
- Genito-urinary tract infections, such as cystitis (infection of the bladder), urethritis (infection of the urethra), pyelonephritis (infection of the kidney).
- 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.

2. What you need to know 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** (see section 6).
- If you have a previous history of amoxicillin/clavulanic-associated jaundice (yellowing of the skin)/liver dysfunction.

Warnings and precautions

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 (sexually transmitted infection).

- 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 (kidney), hepatic (liver) and haematopoietic function (hematopoiesis is the process through which the body manufactures blood cells), 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 (condition commonly known as glandular fever), 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 (a type of blood cancer) since they are especially susceptible to amoxicillin induced skin rashes.

Other medicines with AURO AMOXICLAV:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

AURO AMOXICLAV interacts with:

- probenecid and allopurinol (medicine for gout),
- oral contraceptives,
- tetracyclines (an antibiotic)
- methotrexate (a medicine used to treat cancer or rheumatic diseases).

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.

AURO AMOXICLAV with food and drink

AURO AMOXICLAV should be taken immediately before a meal (section 3).

Pregnancy and breastfeeding and fertility

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Use in Pregnancy:

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

Breastfeeding

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.

Driving and using machines

It is not always possible to predict to what extent **AURO AMOXICLAV** may interfere with the daily activities of a patient. **AURO AMOXICLAV** may cause allergic reactions, dizziness or convulsions or gastrointestinal effects which may influence mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision. Patients should therefore ensure that they do not engage in daily activities until they are aware of the measure to which **AURO AMOXICLAV** affects them (see to section 4).

AURO AMOXICLAV

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take AURO AMOXICLAV

Do not share medicines prescribed for you with any other person.

Always take **AURO AMOXICLAV** exactly as your doctor or pharmacist has told 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.

Your doctor will tell you how long your treatment with **AURO AMOXICLAV** will last. Do not stop treatment early because. If you have the impression that the effect of **AURO AMOXICLAV** is too strong or too weak, tell your doctor or pharmacist.

The usual dose is:

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 clavulanic 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:

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

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.

If you forget to take AURO AMOXICLAV:

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

If you stop taking AURO AMOXICLAV

Do not stop treatment early.

Finish all your tablets, even if you feel better.

4. Possible side effects

AURO AMOXICLAV can have side effects.

Not all side effects reported for this **AURO AMOXICLAV** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this **AURO AMOXICLAV**, please consult your health care provider for advice.

If any of the following happens, stop taking / using **AURO AMOXICLAV** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting
- inflammation of the protective membrane surrounding the brain (aseptic meningitis)

- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome)

These are all very serious side effects. If you have them, you may have had a serious reaction to **AURO AMOXICLAV**. You may need urgent medical attention or hospitalisation.

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 (itching) and urticaria (hives), serum sickness-like syndrome (characterized by skin rash, joint stiffness, joint pain, facial and extremity swelling, and fever), erythema multiforme (central dark spots surrounded by a paler area, with a dark ring around the edge), rare cases of Stevens-Johnson syndrome (a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals), hypersensitivity vasculitis (extreme reaction to a medicine)
and less frequently bullous exfoliative dermatitis (bullous exfoliative dermatitis) and toxic epidermal nercrolysis (extensive peeling of the skin (more than 30 % of the body surface)) 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 (inflammation of the kidneys) can occur less frequently.
Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)

Gastrointestinal reactions:

Nausea, vomiting, diarrhoea, gastritis (upset stomach), stomatitis (inflammation of the mouth), glossitis (inflammation of the tounge), black 'hairy' tongue, enterocolitis (inflammation of the small and large intestine), mucocutaneous candidiasis (mucocutaneous candidiasis) and antibiotic-associated colitis (inflammation of the mucosal lining of the colon (including pseudomembranous colitis (a severe inflammation of the inner lining of the colon) and haemorrhagic colitis (inflammation of the colon causing abdominal pian an watery diarhoea)). If gastro-intestinal reactions are evident, they may be reduced by taking **AURO AMOXICLAV** at the start of a meal.

Hepatic (liver) effects:

Hepatitis (inflammation of the liver) and cholestatic jaundice (yellowing of the skin) 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) (presence of liver enzymes indicating liver injury or damage) has been noted in patients treated with **AURO AMOXICLAV,** but the significance of these findings is unknown.

Renal (kidney) effects:

Crystalluria (crystals in urine leading to acute renal injury) has been reported. The frequency thereof is unknown.

Haematological (bood and blood-forming tissues) effects:

Haemolytic anaemia (low number of red blood cells), reversible thrombocytopenia (reduction in blood platelets causing unusual bruising or bleeding (thrombocytopenia), thrombocytopenic purpura, eosinophilia (increased white blood cells), reversible leucopenia (decrease of white

blood cells or blood pigment / haemoglobin) and agranulocytosis (severe decrease in white blood cells) 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.

Central Nervous System (CNS) Effects:

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

Inflammation of the membranes that surround the brain and spinal cord (aseptic meningitis)

Drug-induced enterocolitis syndrome (DIES):

DIES has been reported mainly in children receiving amoxicillin. It is a certain kind of allergic reaction with the leading symptom of repetitive vomiting (1-4 hours after drug use). Further symptoms could comprise abdominal pain, lethargy, diarrhoea, and low blood pressure.

Frequent side effects:

- mucocutaneous candidiasis (thrush - a yeast infection of the vagina, mouth or skin folds caused by Candida)
- thrombocytopenic purpura (easy bruising, bleeding and pinpoint-sized reddish-purple spots on the lower legs), eosinophilia (increased white blood cells)
- headache, dizziness, hot flushes
- nausea, vomiting, diarrhoea, indigestion, abdominal pain, gastritis (inflammation of the lining of the stomach), stomatitis (painful swelling and sores inside the mouth), enterocolitis (inflammation of the small and large intestine)
- skin rashes, pruritus (itching), urticaria (hives), erythema multiforme (central dark spots surrounded by a paler area, with a dark ring around the edge),
- abnormal taste

- vaginitis (an inflammation of the vagina that can result in discharge, itching and pain)
- tiredness

Less frequent

- reversible leucopenia (decrease of white blood cells or blood pigment / haemoglobin), reversible thrombocytopenia (reduction in blood platelets causing unusual bruising or bleed), serum sickness-like syndrome (characterized by skin rash, joint stiffness, joint pain, facial and extremity swelling, and fever), ~~rare~~ less frequent cases of Stevens-Johnson syndrome (a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals), toxic epidermal nercrolysis (extensive peeling of the skin (more than 30 % of the body surface))
- convulsions (may occur with impaired renal function or in those receiving high doses
- glossitis (inflammation of the tounge), black 'hairy' tongue
- hepatitis (inflammation of the liver), cholestatic jaundice (yellowing of the skin), presence of liver enzymes indicating liver injury or damage.
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Frequency not known:

- intestinal bacterial overgrowth (result in multiple intestinal symptoms like abdominal pain, bloating, diarrhea, and rarely malabsorption)
- haemolytic anaemia (low number of red blood cells), prolongation of bleeding time and prothrombin time (test measures how fast a blood sample forms a clot), agranulocytosis (severe decrease in white blood cells)
- inflammation of tubes in the kidney), hypersensitivity vasculitis (extreme reaction to a medicine), bullous exfoliative dermatitis (bullous exfoliative dermatitis)
- reversable hyperactivity
- aseptic meningitis
- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome)
- antibiotic-associated colitis (inflammation of the mucosal lining of the colon (including pseudomembranous colitis (a severe inflammation of the inner lining of the colon) and

haemorrhagic colitis (inflammation of the colon causing abdominal pian an watery diarhoea)). If gastro-intestinal reactions are evident, they may be reduced by taking **AURO AMOXICLAV** at the start of a meal, DIES has been reported mainly in children receiving amoxicillin. It is a certain kind of allergic reaction with the leading symptom of repetitive vomiting (1-4 hours after drug use). Further symptoms could comprise abdominal pain, lethargy, diarrhoea, and low blood pressure

- exanthemous pustulosis (a red, scaly rash with bumps under the skin and blisters), flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
- rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)
- crystaluria (crystals in urine leading to acute renal injury)
- tooth discolouration
- a moderate raise in Aspartate transaminase (AST) and/or Alanine transaminase (ALT) (presence of liver enzymes indicating liver injury or damage) has been noted in patients treated with **AURO AMOXICLAV**, but the significance of these findings is unknown
- thrombocytosis (low number of cells involved in blood clotting)
- interstitial nephritis

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **AURO AMOXICLAV.**

5. How to store 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).

6. Contents of the pack and other information

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, isopropyl alcohol, magnesium stearate, methylene chloride, opadry white, silica colloidal anhydrous, sodium starch glycolate.

What AURO AMOXICLAV looks like and contents of the pack

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.

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.

Holder of Certificate of Registration

Aurogen South Africa (Pty) Ltd

Woodhill Office Park, Building 1, 53 Phillip Engelbrecht Avenue

Meyersdal Ext. 12, 1448

Johannesburg, South Africa

Telephone no.: +27 11 867 9100

This leaflet was last revised in

16 March 2026

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