

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

AMOXICLAV 125-31,25 mg/5 ml AURO (Powder for oral Suspension)

AMOXICLAV 250-62,5 mg/5 ml AURO (Powder for oral Suspension)

Amoxicillin and clavulanic acid

Sugar free

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

AMOXICLAV AURO.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **AMOXICLAV AURO** 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 **AMOXICLAV AURO** is and what it is used for
2. What you need to know before you **AMOXICLAV AURO**
3. How to **AMOXICLAV AURO**
4. Possible side effects
5. How to store **AMOXICLAV AURO**
6. Contents of the pack and other information

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

AMOXICLAV AURO is a combination of a penicillin, amoxicillin and a beta-lactamase inhibitor, clavulanic acid. Penicillins and beta-lactamase inhibitors are used to treat many different infections caused by bacteria, such as sinusitis, bronchitis, pneumonia, tonsillitis, ear infections, urinary tract infections and infections of the skin. Amoxicillin works by killing

the bacteria. Clavulanic acid is added to the amoxicillin to protect the amoxicillin from certain substances (enzymes) that will destroy the amoxicillin before it can kill the bacteria.

2. What you need to know before you AMOXICLAV AURO

Do not take AMOXICLAV AURO:

- If you have ever had an allergic reaction to amoxicillin, to any other penicillin antibiotic, or to a cephalosporin antibiotic.
- If you have previously had jaundice (yellow pigmentation of skin and eyes) and/or liver disease when using the combination of amoxicillin and clavulanic acid.

Take special care with AMOXICLAV AURO:

- A serious form of diarrhoea (pseudomembranous colitis) may occur. Contact your doctor right away if stomach pain or cramps, severe diarrhoea, or bloody stools occur.
- If you are taking high doses, make sure you drink plenty of fluids.
- Keep all appointments with your doctor and laboratory. If you are taking **AMOXICLAV AURO** for a long period of time, your doctor may order certain tests to check your kidneys, liver and blood.
- If you are having tests on or checking your urine for sugar, let the doctor know that you are on **AMOXICLAV AURO**. This is because **AMOXICLAV AURO** can affect the results of these tests.
- Use of **AMOXICLAV AURO** may result in an infection that occurs while you are being treated for an infection. If this occurs, **AMOXICLAV AURO** should be stopped and suitable treatment given.

Before using **AMOXICLAV AURO**, tell your doctor if you:

- have allergies or a history of allergies – Patients with a history of allergies are more likely to have a allergic reaction to **AMOXICLAV AURO** which can be serious and possibly fatal. Tell your doctor about any previous allergic reactions to penicillins, cephalosporins, other medicines, food, or other substances.

Stop taking **AMOXICLAV AURO** and get emergency help if you have any of these signs of an allergic reaction: hives; difficulty breathing; swelling of your face, lips, tongue or throat.

- have infectious mononucleosis (glandular fever) or a sore throat.
- have syphilis

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- have lymphatic leukemia (cancer of the blood)
 - have liver disease
 - have kidney disease
 - are breast-feeding
 - have a blood clotting disorder

Other medicines with **AMOXICLAV AURO**

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

Some medicines may interact with amoxicillin and clavulanic acid. Before taking

AMOXICLAV AURO, tell your doctor if you are using any of the following medicines:

- oral contraceptives – Your oral contraceptive may not work properly. You will need to use extra contraceptive precautions, such as using a condom. If you need any advice, talk to your doctor or pharmacist.
- Allopurinol and probenecid, a medicine used for gout. Concomitant use of probenecid may reduce the excretion of amoxicillin and is not recommended.
- any medicine to stop blood clots, such as warfarin.
- tetracycline antibiotics.
- another antibiotic.
- methotrexate (used to treat cancer and severe psoriasis), penicillins may reduce the excretion of methotrexate causing a potential increase in side effects.

If you are using any of these medicines, you may not be able to take **AMOXICLAV AURO**, or you may need dosage adjustments or your doctor may need to monitor you carefully for side-effects.

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

AMOXICLAV AURO with food and drink

AMOXICLAV AURO should be taken immediately before a meal.

Pregnancy and breastfeeding and fertility

- The safety of this medicine in pregnant women has not been confirmed - Tell your doctor if you are pregnant or plan to become pregnant.
- **AMOXICLAV AURO** can pass into breast milk and may cause a yeast infection, diarrhoea, or allergic reaction in a nursing baby. Do not use this medication without telling your doctor if you are breast-feeding a baby.

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.

3. How to AMOXICLAV AURO

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

- **AMOXICLAV AURO** should be taken at the start of a meal, to help prevent stomach upset.
- Shake the liquid well before each use to mix the medication evenly.
- To be sure you get the correct dose, measure the liquid with a marked measuring spoon.
- Take this medication for the entire length of time, prescribed by your doctor.
- The usual dose of **AMOXICLAV AURO** in children is 25 - 50 mg/kg/day, taken in divided doses every 8 hours (three times a day).
- The dose for children is based on body weight and must be determined by your doctor.
- Tell your doctor if you suffer from kidney disease – your dosage may need to be adjusted.

If you take more AMOXICLAV AURO than you should:

Overdose symptoms may include queasiness or feeling that one is about to vomit, vomiting, diarrhoea, or crystals in the urine, which may be seen as cloudy urine, or problems passing urine.

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 AMOXICLAV AURO:

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

If you stop taking AURO AMOXICLAV

Do not stop treatment early.

Finish all your medicine, even if you feel better

4. Possible side effects

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.

AMOXICLAV AURO can have side-effects.

Get emergency medical help at once if you have any of these signs of an allergic reaction:

- hives
- difficulty breathing
- swelling of your face, lips, tongue, or throat.
- 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)

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- Rash with blisters arranged in a circle with central crusting or like a string of pearls
(linear IgA disease)

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

Call your doctor at once if you have any of these serious side-effects:

- high temperature (fever), chills, a sore throat or other signs of an infection, or if you bruise easily. These may be signs of a problem with your blood cells.
- Unusual bleeding - your blood may take longer to clot than it normally would. You may notice this if you cut yourself or have a nosebleed.
- pale skin, excessive tiredness.
- a delayed allergic reaction, some signs include: rashes, fever, joint pains and enlargement of the lymph nodes.
- a skin reaction known as “erythema multiforme”, where you may develop: itchy reddish purple patches on the skin. You may have a fever and be very tired.
- other severe skin reactions can include: changes in skin colour, bumps under the skin, blistering, pustules, peeling, redness, pain, itching, scaling. These may be associated with fever, headaches, and body aches.
- rash or pinpoint flat red round spots under the skin surface or bruising of the skin.
This is due to inflammation of blood vessel walls due to an allergic reaction. It can be associated with joint pain and kidney problems.
- convulsions (seizures), seen in patients on high doses or with kidney problems.
- nausea, stomach pain, low fever, loss of appetite, yellowing of the skin or eyes, dark urine, or clay-coloured stools.
- inflammation of the large bowel (colon) with severe diarrhoea that is watery or bloody, pain and fever.
- urinating less than usual or not at all.

Other possible side-effects are:

- mild skin rash
- hyperactivity
- dizziness
- headache
- feeling sick (nausea)
- being sick (vomiting)
- diarrhoea
- stomach/abdominal pain
- indigestion
- taste disturbances
- teeth may appear stained, usually returning to normal with brushing
- sore mouth or tongue
- black, or “hairy” tongue
- thrush (white patches inside your mouth)
- vaginal itching or discharge
- hot flushes
- crystals in the urine (crystalluria), which may be seen as a cloudy urine, or difficulty or discomfort in passing urine. Make sure you drink plenty of fluids to reduce the chance of these symptoms

Frequency not known:

- 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.

Tell your doctor if any of the above side-effects are severe, bothersome, do not go away or about any concerns you have while taking **AMOXICLAV AURO**.

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 **AMOXICLAV AURO**.

5. How to store AMOXICLAV AURO

Store all medicines out of the reach of children.

For dry powder:

Store below 30 °C (room temperature) and away from moisture (not in the bathroom).

For reconstituted suspension:

Once reconstituted, the suspension (liquid medication) should be kept in a refrigerator. Throw away any unused medication after 7 days. Do not freeze. Shake the bottle well before use.

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 AMOXICLAV AURO contains:

The active substances are amoxicillin and clavulanic acid.

AMOXICLAV 125-31,25 mg/5 ml AURO:

Each 5 ml (after reconstitution) contains: Amoxicillin trihydrate, equivalent to amoxicillin 125 mg
and potassium clavulanate equivalent to clavulanic acid 31.25 mg

AMOXICLAV 250-62,5 mg/5 ml AURO:

Each 5 ml (after reconstitution) contains: Amoxicillin trihydrate, equivalent to amoxicillin 250 mg
and potassium clavulanate equivalent to clavulanic acid 62.5 mg

The other ingredients contained in **AMOXICLAV AURO** are aspartame, hypromellose, silica
colloidal anhydrous, silicon dioxide, strawberry guarana flavour, succinic acid, silicon dioxide
syloid, and xanthum gum.

What AMOXICLAV AURO looks like and contents of the pack

AMOXICLAV 125-31,25 mg/5 ml AURO:

White to off white granular powder forming a white to off white suspension with a strawberry
flavour on constitution with water.

AMOXICLAV 250-62,5 mg/5 ml AURO:

White to off white granular powder forming a white to off white suspension with a strawberry
flavour on constitution with water.

AMOXICLAV 125-31,25 mg/5 ml AURO:

One 150 ml heavy weight HDPE translucent, round bottle closed with a screw cap packed
in a printed carton with a package insert.

(100 ml of suspension after reconstitution)

One 200 ml Amber coloured, round glass bottle closed with a screw cap packed in a
printed carton with a package insert.

(100 ml of solution after reconstitution).

AMOXICLAV 250-62,5 mg/5 ml AURO:

One 150 ml heavy weight HDPE translucent, white opaque round bottle closed with a
screw cap packed in a printed carton with a package insert.

(100 ml of suspension after reconstitution).

One 200 ml Amber coloured, round glass bottle closed with a screw cap packed in a printed carton with a package insert.

(100 ml of solution after reconstitution)

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Can be obtained on the SAHPRA website.