

Applicant/PHCR: AUROGEN SOUTH AFRICA (PTY) LTD
Product proprietary name: AURO AMOXICILLIN SUSPENSION 125 mg/5 ml / 250 mg/5 ml
Dosage form and strength: POWDER FOR SUSPENSION 125 mg/5 ml / 250 mg/5 ml
Amended: 29/01/2021

PATIENT INFORMATION LEAFLET (Clean Copy)

S4

AURO AMOXICILLIN SUSPENSION 125 mg/5 ml (Powder for Suspension)

AURO AMOXICILLIN SUSPENSION 250 mg/5 ml (Powder for Suspension)

Amoxicillin trihydrate

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

- 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 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 AURO AMOXICILLIN SUSPENSION CONTAINS

The active substance is amoxicillin.

AURO AMOXICILLIN SUSPENSION 125 mg/5 ml:

Each 5 ml of reconstituted suspension contains amoxicillin trihydrate equivalent to amoxicillin 125 mg.

Sugar Free.

Preservative: Sodium benzoate.....0.07 % *m/v*

AURO AMOXICILLIN SUSPENSION 250 mg/5 ml:

Each 5 ml of reconstituted suspension contains amoxicillin trihydrate equivalent to amoxicillin 250 mg.

Sugar Free.

Preservative: Sodium benzoate.....0.07 % *m/v*

The other ingredients contained in **AURO AMOXICILLIN SUSPENSION** are saccharin sodium, disodium edetate, xanthan gum, lemon flavour, peach flavour, strawberry guarana flavour, silica colloidal anhydrous, silicon dioxide and sorbitol.

2. WHAT AURO AMOXICILLIN SUSPENSION IS USED FOR

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AURO AMOXICILLIN SUSPENSION is an antibiotic in the penicillin group of medications. It works by eliminating bacteria in your body. **AURO AMOXICILLIN SUSPENSION** is used to treat infections caused by bacteria, such as bronchitis, pneumonia, infections of the ears, nose, throat, urinary tract and skin. It is also used in combination with other medications to eliminate *H. pylori*, a bacteria that causes ulcers. It is also used to stop infections when you have a tooth removed or other surgery.

3. BEFORE YOU TAKE AURO AMOXICILLIN SUSPENSION

Do not take AURO AMOXICILLIN SUSPENSION:

- If you have ever had an allergic reaction to amoxicillin, to any other penicillin antibiotic, or to a cephalosporin antibiotic.
- **Take special care with AURO AMOXICILLIN SUSPENSION:**
- A serious form of diarrhoea-may occur. Contact your doctor right away if stomach pain or cramps, severe diarrhoea, or bloody stools occur.
- If you are having tests on or checking your urine for sugar, let the doctor know that you are on **AURO AMOXICILLIN SUSPENSION**. This is because **AURO AMOXICILLIN SUSPENSION** can affect the results of these tests.
- If you are taking high doses, make sure you drink plenty of fluids.
- Before using **AURO AMOXICILLIN SUSPENSION** , tell your doctor if you:
 - Are allergic to amoxicillin, penicillins, cephalosporins, any other medications, or have a history of allergy
 - have mononucleosis (glandular fever) or a sore throat
 - have a blood clotting disorder
 - have liver disease
 - have kidney disease
 - have syphilis
 - have lymphatic leukaemia (cancer of the blood)
 - pregnant or plan to become pregnant, or are breast-feeding.

Taking AURO AMOXICILLIN SUSPENSION with food:

AURO AMOXICILLIN SUSPENSION may be taken with or without food.

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Pregnancy and Breast-feeding:

- The safety of **AURO AMOXICILLIN SUSPENSION** in pregnancy has not been confirmed.
- **AURO AMOXICILLIN SUSPENSION** passes into breast milk, and may harm a nursing baby.
Mothers taking **AURO AMOXICILLIN SUSPENSION** should not breast-feed their babies.

Driving and using machinery:

Treatment with **AURO AMOXICILLIN SUSPENSION** is not known to affect your ability to drive and use machines.

If you are pregnant or breast-feeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice before taking **AURO AMOXICILLIN SUSPENSION**

Taking other medicines with AURO AMOXICILLIN SUSPENSION :

Some medicines may interact with amoxicillin. Before taking **AURO AMOXICILLIN SUSPENSION** , 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, a medicine used for gout.
- any medicine to stop blood clots, such as warfarin.
- tetracycline antibiotics.

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

Always tell your healthcare professional if you are taking any other medicine.
(This includes complementary or traditional medicines.)

4. HOW TO TAKE AURO AMOXICILLIN SUSPENSION

Always take **AURO AMOXICILLIN SUSPENSION** exactly as your doctor has instructed you. You

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should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **AURO AMOXICILLIN SUSPENSION** is too strong or too weak, talk to your doctor or pharmacist.

- Take this medication only as directed by your doctor.
- Do not take more or less of it or take it more often than prescribed by your doctor.
- Take this medication for the entire length of time prescribed by your doctor.
- Treatment should be continued for 2 to 3 days after the symptoms have gone.
- **AURO AMOXICILLIN SUSPENSION** is usually taken every 8 hours (three times a day).
- Adults and children weighing more than 40 kg: The usual dosage is 750 mg to 3 g per day, given in equally divided doses. The maximum recommended dose is 6 g per day, given in equally divided doses.
- Children weighing less than 40 kg: For children, the dose is based on body weight.
- To stop infection during surgery – A dose will be given before the procedure. Your doctor, pharmacist or nurse can give you more details.
- Tell your doctor if you suffer from kidney disease – your dosage may need to be adjusted.

If you take more AURO AMOXICILLIN SUSPENSION 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 over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take AURO AMOXICILLIN SUSPENSION :

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.

5. POSSIBLE SIDE-EFFECTS

AURO AMOXICILLIN SUSPENSION can have side-effects.

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- Get emergency medical help if you have any of these **signs of an allergic reaction**:
 - hives, difficulty breathing, swelling of your face, lips, tongue, or throat.
- Call your doctor at once if you have any of these serious side-effects:
 - high temperature (fever), 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.
 - pale skin
 - excessive tiredness
 - a skin reaction”, where you may develop: itchy reddish purple patches on the skin.
 - 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).
 - yellowing of the skin or eyes.
 - dark urine, clay-coloured stools, urinating less than usual or not at all.
 - severe diarrhoea that is watery or bloody.
- Tell your doctor if any of the side-effects below are severe, bothersome, do not go away or about any concerns you have while taking **AURO AMOXICILLIN SUSPENSION**.
 - skin rash
 - hyperactivity, dizziness, headache
 - nausea, vomiting
 - diarrhoea, indigestion, stomach pain
 - 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
 - crystals in the urine, which may be seen as a cloudy urine, or difficulty or discomfort in passing

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urine. Make sure you drink plenty of fluids to reduce the chance of these symptoms.

- the blood may take longer to clot than it normally would. You may notice this if you cut yourself or have a nosebleed.

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 AMOXICILLIN SUSPENSION

Store all medicines out of reach of children.

For dry powder:

Store at or below 30 °C (room temperature).

For Reconstituted Suspension:

Once reconstituted, the suspension (liquid medication) should be kept in a refrigerator. Throw away any unused medication after 14 days. 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).

7. PRESENTATION OF AURO AMOXICILLIN SUSPENSION

AURO AMOXICILLIN SUSPENSION 125 mg/5 ml:

The granular powders are packed in a 150 ml plastic translucent, round bottle with a 28 mm white propylene neck closed with a 28 mm screw cap with induction sealing wad.

(100 ml of suspension after reconstitution).

Pack size: One 150 ml plastic translucent, round bottle closed with a white propylene screw cap with an induction sealing wad, packed in a printed carton with a package insert.

AURO AMOXICILLIN SUSPENSION 250 mg/5 ml:

The granular powders are packed in a 150 ml plastic translucent, round bottle with a 28 neck closed with a 28 mm mm white propylene screw cap with induction sealing wad.

(100 ml of suspension after reconstitution).

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Pack size: One 150 ml plastic translucent, round bottle closed with a white propylene screw cap with an induction sealing wad, packed in a printed carton with a package insert.

8. IDENTIFICATION OF AURO AMOXICILLIN SUSPENSION

AURO AMOXICILLIN SUSPENSION 125 mg/5 ml:

For Dry Powder: White to off white granular powder.

For Reconstituted Suspension: White to off white suspension with citrus flavour.

AURO AMOXICILLIN SUSPENSION 250 mg/5 ml:

For Dry Powder: White to off white granular powder.

For Reconstituted Suspension: White to off white suspension with citrus flavour.

9. REGISTRATION NUMBERS/REFERENCE NUMBERS

AURO AMOXICILLIN SUSPENSION 125 mg/5 ml: 42/20.1.2/0337

AURO AMOXICILLIN SUSPENSION 250 mg/5 ml: 42/20.1.2/0338

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Aurogen South Africa (Pty) Ltd

Woodhill Office Park, Building 1

53 Phillip Engelbrecht Avenue

Meyersdal, Ext 12, 1448

Johannesburg, South Africa

11. DATE OF PUBLICATION

23 November 2017

DATE OF REVISION:

17 September 2021