

Applicant: Aurogen South Africa (Pty) LTD
Product Name: AURO AMPICILLIN 500 mg
Dosage form and strength: INJECTION 500 mg

Date: 16/02/2024

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

AURO AMPICILLIN INJECTION 500 mg (Powder for Injection)

Ampicillin sodium

Sugar free

Read all of this leaflet carefully before AURO AMPICILLIN INJECTION is administered to you.

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

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1. What AURO AMPICILLIN INJECTION is and what it is used for

AURO AMPICILLIN INJECTION is used for the treatment of conditions caused by the Gram-positive non- penicillinase producing Staphylococci, haemolytic and non-haemolytic streptococci, *Diplococcus pneumoniae*, *Clostridia sp.* and *Streptococcus faecalis*. Also the Gram-negative cocci *Neisseria spp.*, *Haemophilus influenzae*, *Escherichia coli*, *Proteus mirabilis* and many strains of Brucellae, *Salmonellae* and *Shigellae*.

2. What you need to know before you take AURO AMPICILLIN INJECTION

Do not take AURO AMPICILLIN INJECTION:

- If you are hypersensitive to penicillin or cephalosporins. Cases of cross-sensitivity have been reported.
- In the neonatal period, to babies born of hypersensitive mothers.

Warnings and precautions

Take special care with AURO AMPICILLIN INJECTION:

Before receiving AURO AMPICILLIN INJECTION:

- Tell your doctor if you are allergic to penicillins, cephalosporins, any other medications, or have a history of allergy. Serious and sometimes fatal allergic reactions are more likely to occur in patients with a history of penicillin allergy or other allergies.

Your healthcare professional should observe you for at least one hour after you have been administered **AURO AMPICILLIN INJECTION**.

AURO AMPICILLIN INJECTION should be stopped, and emergency help given if you have any of these signs of a severe allergic reaction: difficulty breathing; swelling of your face, lips, tongue or throat.

- Tell your doctor if you have syphilis, since a reaction called the “Jarisch-Herxheimer reaction” may occur shortly after starting treatment with **AURO AMPICILLIN INJECTION**. Symptoms of this reaction include fever, chills and headaches.

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- Tell your doctor if you are on a low sodium (salt) diet – **AURO AMPICILLIN INJECTION** contains sodium.
- Tell your doctor if you have kidney problems. Your doctor may need to reduce your dosage.
- Tell your doctor if you have congestive heart failure.
- Tell your doctor if you have infectious mononucleosis (glandular fever), lymphatic leukaemia (cancer of the blood), or HIV infection, or if you are taking a medicine called allopurinol. There is an increased possibility of skin rashes occurring in patients taking **AURO AMPICILLIN INJECTION** with these conditions.
- Tell your doctor if you have a bleeding or blood clotting disorder.
- If a skin rash occurs, **AURO AMPICILLIN INJECTION should be stopped.**
- A serious form of diarrhoea (pseudomembranous colitis) may develop if you use **AURO AMPICILLIN INJECTION** for a long period of time. Contact your doctor right away if stomach pain or cramps, severe diarrhoea, or bloody stools occur.
- During long-term treatment, your doctor may want to take routine blood tests to monitor your kidney function, liver function and levels of blood cells.
- Following long-term treatment, numbness; tingling; pins and needles has rarely been reported.
- **AURO AMPICILLIN INJECTION** can cause interference in some tests for glucose in urine. Penicillins which are excreted in urine can cause a false-positive result. Your doctor will request a test which is not affected by penicillins.
- **AURO AMPICILLIN INJECTION** may interfere with certain laboratory tests. Be sure your doctor and laboratory personnel know you are using **AURO AMPICILLIN INJECTION.**
- If you are receiving high doses, make sure that you take enough fluids.

Receiving AURO AMPICILLIN INJECTION with food, drink and alcohol:

- It is recommended that alcohol should be avoided during and for several days after treatment with **AURO AMPICILLIN INJECTION.**

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Pregnancy and Breastfeeding:

If you are pregnant or breast feeding your baby, please consult your doctor, pharmacist or other health care professional for advice before receiving **AURO AMPICILLIN INJECTION**.

- Safety in pregnancy and breast-feeding has not been established.
- **AURO AMPICILLIN INJECTION** pass into breast milk. The use of **AURO AMPICILLIN INJECTION** by breast-feeding mothers may cause sensitivity (allergic reaction) such as diarrhoea, thrush and skin rash in the baby.

Driving and using machinery:

AURO AMPICILLIN INJECTION may cause dizziness. If you experience these symptoms while taking **AURO AMPICILLIN INJECTION** do not drive and do not use tools and machines.

Other medicines with AURO AMPICILLIN INJECTION:

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

Some medicines may interact with **AURO AMPICILLIN INJECTION**.

Before taking **AURO AMPICILLIN INJECTION**, tell your doctor if you are using any of the following medicines: Lignocaine – Lignocaine should only be used together with **AURO AMPICILLIN INJECTION**, when **AURO AMPICILLIN INJECTION** is injected into a muscle, and must not be given into a vein.

- Preparations for thinning blood (e.g. warfarin, heparin) – Your doctor may want to monitor your blood clotting time more frequently if you are receiving anticoagulant treatment in combination with **AURO AMPICILLIN INJECTION**.
- NSAIDs (non-steroidal anti-inflammatory drugs) or salicylates (e.g. aspirin) – The risk of bleeding is increased when these medicines are used together with **AURO AMPICILLIN INJECTION**.
- Aminoglycoside antibiotics (e.g. gentamicin) and cephalosporin antibiotics – **AURO AMPICILLIN INJECTION** should not be mixed in the same syringe or administration set with these antibiotics.

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- Methotrexate, used to treat cancer – **AURO AMPICILLIN INJECTION** may decrease the removal of methotrexate from the body, increasing the risk of its side-effects. Your doctor may want to monitor the amount of methotrexate in your blood if you are receiving methotrexate treatment in combination with **AURO AMPICILLIN INJECTION**.
- ACE inhibitors, potassium-sparing diuretics, potassium containing medicines or potassium supplements – Use of these medicines together with **AURO AMPICILLIN INJECTION** may cause too much potassium in the blood, especially in patients with kidney problems.
- Allopurinol, medicine for gout - There is an increased possibility of skin rashes occurring in patients taking **AURO AMPICILLIN INJECTION** together with allopurinol.
- Oral contraceptives – **AURO AMPICILLIN INJECTION** may decrease the effectiveness of birth control pills. Use an alternative or additional method of birth control while taking **AURO AMPICILLIN INJECTION** to protect against pregnancy.

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

3. How to use AURO AMPICILLIN INJECTION

- **AURO AMPICILLIN INJECTION** is usually given as an injection at your doctor's office, hospital, or clinic.
- **AURO AMPICILLIN INJECTION** may be given by injection into a muscle or vein or as directed by your doctor.

If you have the impression that the effect of **AURO-AMPICILLIN INJECTION** is too strong or too weak, talk to your doctor or pharmacist.

If you take given more AURO-AMPICILLIN than you should receive:

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

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As **AURO-AMPICILLIN** is administered by a medical professional, it is unlikely that you will be given too much or too little.

Overdose symptoms may include increased gastrointestinal side effects such as nausea, vomiting and diarrhea.

If a dose of AURO AMPICILLIN INJECTION is missed:

Your medication will usually be given to you by a healthcare professional. If you think that a dose has been skipped, please tell your doctor or nurse.

4. POSSIBLE SIDE EFFECTS

AURO AMPICILLIN INJECTION can have side effects.

Not all side effects reported for **AURO AMPICILLIN INJECTION** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving **AURO AMPICILLIN INJECTION**, please consult your doctor, pharmacist.

Get emergency medical help if you have any of these **signs of a severe allergic reaction:**

- Urticaria (hives); difficulty breathing; swelling of your face, lips, tongue, or throat, difficulty in swallowing or breathing.

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

- Diarrhoea that is watery or bloody
- Easy/unusual bruising or bleeding, nose bleeds
- Severe skin rash or hives; widespread redness of the skin, blistering or severe peeling of the skin
- Seizures (convulsions)
- Hives, fever, joint pains
- Fever, chills, headache

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- Yellow pigmentation of skin and eyes
- Urinating less than usual or not at all

Tell your doctor if you notice any of the following side-effects and they worry you or if any of these symptoms are severe or do not go away:

- Too few white blood cells (sore throat and fever); anaemia (tiredness, being short of breath and looking pale); numbness, tingling, pins and needles; thrush (white patches inside your mouth or throat, vaginal itching or discharge); increased muscular activity; dizziness; nausea (queasiness, feeling that one is about to vomit); vomiting; diarrhoea; inflammation of the mouth; inflammation of the tongue; black hairy tongue; heartburn; inflammation of the blood vessels, crystals found in the urine.

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 "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8> . By reporting side effects, you can help provide more information on the safety of **AURO AMPICILLIN INJECTION**.

5. How to store AURO AMPICILLIN INJECTION

Store all medicines out of the reach and sight of children.

Store at or below 30 °C in a dry place.

Return all unused medicine to your pharmacist

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

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6. Contents of the pack and other information

The active substance is Ampicillin sodium.

AURO AMPICILLIN INJECTION 500 mg:

Each vial contains Ampicillin sodium equivalent to 500 mg Ampicillin. Sugar free.

What AURO AMPICILLIN INJECTION looks like and contents of the pack

AURO AMPICILLIN INJECTION 500 mg is packaged in:

A 7.5 mL clear, transparent, tubular glass vial fitted with a 20 mm grey colour bromo butyl rubber stopper and sealed with a 20 mm dark green coloured PP disc.

Pack size:

1. Single vial packed in a printed carton with a package insert.
2. 10 vials packed in a plain E-fluted box with partition and package insert.
3. 50 vials packed in a plain E-fluted box with partition and package insert.
4. 100 vials packed in a plain E-fluted box with partition and package insert.

What AURO AMPICILLIN INJECTION 500 mg looks like:

White to off white crystalline powder filled in 7.5 mL tubular vial, stoppered with 20 mm grey colour bromo butyl rubber stopper and sealed with 20 mm dark green coloured PP disc.

Registration number

AURO AMPICILLIN INJECTION 500 mg: 41/20.1.2/0122

Holder of Certificate of Registration

Aurogen South Africa (Pty) Ltd.
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