

Product proprietary name: Indo Amoxicillin 250 (Capsules)
Indo Amoxicillin-500 (Capsules)

Dosage form and strength: Amoxicillin trihydrate equivalent to Amoxicillin 250 mg per capsule
Amoxicillin trihydrate equivalent to Amoxicillin 500 mg per capsule

SCHEDULING STATUS S4

Indo Amoxicillin 250 (250 mg Capsules)

Indo Amoxicillin-500 (500 mg Capsules)

Amoxicillin

Sugar free

Read all of this leaflet carefully before you start taking INDO AMOXYCILLIN

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

1. What INDO AMOXYCILLIN is and what it is used for

INDO AMOXYCILLIN is an antibiotic. The active ingredient is amoxicillin. This belonging to a group of medicines called 'penicillins'.

INDO AMOXYCILLIN is used to treat infections caused by bacteria in different parts of the body. INDO AMOXYCILLIN may also be used in combination with other medicines to treat stomach ulcers.

2. What you need to know before you take INDO AMOXYCILLIN

Do not take INDO AMOXYCILLIN:

- if you are hypersensitive (allergic) to amoxicillin, penicillin or any of the other ingredients of INDO AMOXYCILLIN (listed in section 6).
- if you have ever had an allergic reaction to any antibiotic. This can include a skin rash or swelling of the face or throat.

Warnings and precautions

Take special care with INDO AMOXYCILLIN:

- If you experience allergic reactions like skin rash or swelling of the face or throat or chest pain, your health care provider may want to discontinue INDO AMOXYCILLIN therapy and prescribe alternative therapy. Serious anaphylactic reactions may require immediate emergency treatment.
- If you have kidney problems (dosage adjustment is required).
- If you are not urinating regularly.
- if you have infectious mononucleosis, also known as glandular fever (fever, sore throat, swollen glands and extreme tiredness). A high percentage of patients with mononucleosis who receive amoxicillin develop an erythematous skin rash.
- if you are breastfeeding or intend to breastfeed.

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INDO AMOXYCILLIN passes into breast milk and can be used only with caution during breastfeeding. However, breastfeeding must be stopped if gastrointestinal disorders (diarrhoea, candidiasis or skin rash) occur in the newborn.

- If you develop a Jarisch-Herxheimer's reaction. This reaction has been reported during amoxicillin treatment of syphilis or tick-borne diseases like Lyme disease. Symptoms include high fever, a general feeling of discomfort, illness, or unease, nausea, vomiting, headache, muscle pain, aggravated skin rashes, fast heartbeat, and chills.
- If you develop diarrhoea. This may happen while you are taking INDO AMOXYCILLIN, or within a few months after you stop taking it. This may be a sign of a new infection. If you have diarrhoea that is watery or bloody, stop taking INDO AMOXYCILLIN and call your doctor. Do not use anti-diarrhoea medicine unless your doctor tells you to.
- Periodic assessment of organ function, including renal (kidney), hepatic (liver) and haematopoietic functions (blood), is advisable during prolonged therapy.

If you have or have had any medical conditions, including:

- liver problems;
- lymphatic leukaemia (a type of cancer of the blood and bone marrow);
- a history of seizures;
- a history of allergic problems.

Having urine or blood tests:

If you are having:

- Urine tests (glucose) or blood tests for liver function.
- Oestriol tests (used during pregnancy to check that the baby is developing

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normally).

This is because INDO AMOXYCILLIN can affect the results of these tests.

Other medicines and INDO AMOXYCILLIN

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- Medicine for gout (e.g. allopurinol and probenecid). It may be more likely that you will have an allergic skin reaction or your doctor may decide to adjust the dose of INDO AMOXYCILLIN.
- Oral contraceptives- INDO AMOXYCILLIN can make hormonal contraceptives less effective. You are advised to use supplementary non-hormonal contraceptive measures e.g. condoms.
- Digoxin, a medicine used to treat heart failure.
- Medicines used to prevent blood clots from the coumarin class (e.g. warfarin) as you may need extra blood tests.
- Other antibiotics e.g. tetracyclines, INDO AMOXYCILLIN may be less effective.
- Methotrexate (a medicine used to treat cancer or rheumatic diseases). INDO AMOXYCILLIN may cause an increase in side effects.

INDO AMOXYCILLIN with food and drink and alcohol

INDO AMOXYCILLIN may be taken with meals.

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Pregnancy and breastfeeding

The safety of INDO AMOXYCILLIN during pregnancy as not been established.

If you are pregnant or breastfeeding, 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 INDO AMOXYCILLIN.

INDO AMOXYCILLIN can make hormonal contraceptives less effective. You are advised to use supplementary non-hormonal contraceptive measures e.g. condoms (*see 'Other medicines and INDO AMOXYCILLIN'*).

INDO AMOXYCILLIN is excreted in small quantities into breast milk and it is possible that your baby can experience diarrhoea and fungus infection. Breastfeeding while taking INDO AMOXYCILLIN is not advised.

Driving and using machines

It is not always possible to predict to what extent INDO AMOXYCILLIN may interfere with the daily activities of a patient. INDO AMOXYCILLIN may cause allergic reactions, dizziness or convulsions. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which INDO AMOXYCILLIN affects them (*see section 4 'Possible side effects'*).

INDO AMOXYCILLIN contains sodium

INDO AMOXYCILLIN 250 and INDO AMOXYCILLIN 500 contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

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3. How to take INDO AMOXYCILLIN

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

Always take INDO AMOXYCILLIN exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will advise you on the correct dose for you.

The total daily dose as below is administered in divided doses. The most common regimen is 8 hourly.

The usual dose is:

Adults and children over 40 kg:

Total daily dosage of 750 mg to 3 g administered in divided doses.

Maximum recommended dose: 6 g/day in divided doses.

Respiratory tract infections: 500 mg administered 8 hourly.

Lyme disease: 4 g/day in isolated erythema chronicum migrans and 6 g/day in the case of generalised manifestations, both for a minimum of 12 days.

Gonorrhoea: 3 g with 1 g probenecid.

Eradication of Helicobacter pylori: 750 mg – 1 g in combination treatment given 12 hourly for the eradication of established H pylori infection associated with duodenal ulceration for 7 days.

Children under 40 kg:

20-50 mg/kg/day in divided doses. Maximum recommended dose: 150 mg/kg/day in divided doses.

Lyme disease: 25-50 mg/kg/day in isolated erythema chronicum migrans and 100 mg/kg/day in the case of generalised manifestations, both for a minimum of 12 days.

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Elderly:

No adjustment needed: as for adults unless there is evidence of severe kidney problems.

Kidney problems:

If you have kidney problems the dose might be lower than the usual dose.

Prophylaxis of endocarditis:

Prophylaxis with alternative antibiotics will be considered by your doctor if you have received a penicillin within the previous month or is allergic to penicillin.

Your doctor will tell you how long your treatment with INDO AMOXYCILLIN will last.

If you have the impression that the effect of INDO AMOXYCILLIN is too strong or too weak, tell your doctor or pharmacist.

If you take more INDO AMOXYCILLIN than you should

If you have too much INDO AMOXYCILLIN, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or crystals in the urine, which may be seen as cloudy urine, or problems urinating. Take the medicine to show the doctor.

In the event of over dosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre. Take the medicine to show the doctor.

If you forget to take INDO AMOXYCILLIN

If you forgot to take your medicine, take it as soon as you remember.

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

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If you stop taking INDO AMOXYCILLIN

Do not stop treatment early because the infection can come back. Take INDO AMOXYCILLIN until the treatment is finished, even if you feel better.

4. Possible side effects

INDO AMOXYCILLIN can have side effects.

Not all side effects reported for INDO AMOXYCILLIN are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking INDO AMOXYCILLIN, please consult your health care provider for advice.

If any of the following happens, stop taking INDO AMOXYCILLIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, 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 allergic reaction to INDO AMOXYCILLIN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Serious skin reactions:

- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), and a more severe form, causing extensive peeling of the skin (more than 30 % of the body surface - toxic epidermal necrolysis);
- a widespread red skin rash with small pus-containing blisters (bullous exfoliative dermatitis);
- a red, scaly rash with bumps under the skin and blisters (exanthemous pustulosis);
- 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));
- a skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge – erythema multiforme);
- rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease).

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 medicine intake). Further symptoms could comprise abdominal pain, lethargy, diarrhoea, and low blood pressure.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been reported less frequently:

- inflammation of blood vessels (vasculitis) which may be visible as red or purple raised

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spots on the skin, but can affect other parts of the body;

- fever, joint pain, swollen glands in the neck, armpit or groin;
- inflammation of the large intestine, causing watery diarrhoea usually with blood and mucus, stomach pain and/or fever;
- jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your skin and whites of the eyes appear yellow;
- inflammation of the liver (hepatitis);
- convulsions (in people taking high doses of INDO AMOXYCILLIN or who have kidney problems);
- black tongue which looks hairy.
- nausea;
- vomiting;
- diarrhoea;
- thrush (Candida - a yeast infection of the vagina, mouth or skin folds);
- indigestion;
- dizziness;
- headache;
- low number of cells involved in blood clotting;
- a state of excessive restlessness;
- tooth discolouration;
- low number of red blood cells (haemolytic anaemia);
- crystals in urine leading to acute renal injury;
- inflammation of tubes in the kidney.

The following side effects have been reported but the frequency is unknown:

- increase in some substances (enzymes) produced by the liver;
- severe reduction in the number of white blood cells;

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- low number of red blood cells (haemolytic anaemia);
- low number of cells involved in blood clotting.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

5. How to store INDO AMOXYCILLIN

- Store all medicines out of reach of children.
- Store tightly closed in a dry place at or below 30 °C and protect from light.
- Keep the blisters in the carton until required for use.
- Store in the original package.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label/PRP pouch/container.
- 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 INDO AMOXYCILLIN contains

- The active substance is amoxicillin trihydrate.
- The other ingredients are:

Capsule content

Sodium lauryl sulphate

Purified talc

Magnesium stearate

Capsule shell

Cap:

Carmosine

Sunset Yellow

Indigo Carmine

Titanium Dioxide

Body:

Sunset Yellow

Iron Oxide Yellow

Titanium Dioxide

Shell Composition:

Water

Sodium Lauryl Sulphate

Gelatin

Methyl paraben (Preservative)

Propyl paraben (Preservative)

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Printing ink

Black Iron Oxide

Shellac

Isopropyl Alcohol

Alcohol

Propylene Glycol

What INDO AMOXYCILLIN looks like and contents of the pack

INDO AMOXYCILLIN 250:

Silver aluminium foil/clear, transparent PVC foil blisters in strips of 10 capsules, packed in 20, 100 or 500 capsules per carton.

White round HDPE container with cap containing 100 or 500 capsules.

White polyethylene capsule envelopes (Patient Ready Packs) of different pack sizes.

INDO AMOXYCILLIN 250 - Hard gelatin capsules, size “2” Maroon cap /yellow coloured body, printed with “AMOXY 250” in black ink on the body and cap in a circular manner, containing white to off white granular powder.

INDO AMOXYCILLIN-500:

Silver aluminium foil/clear, transparent PVC foil blisters in strips of 10 capsules, packed in 20, 100 or 500 capsules per carton.

White round HDPE container with cap containing 100 or 500 capsules.

White polyethylene capsule envelopes (Patient Ready Packs) of different pack sizes.

INDO AMOXYCILLIN-500 - Hard gelatin capsules, size “0” Maroon cap /yellow coloured body, printed with “AMOXY 500” in black ink on the body and cap in a circular manner, containing white to off white granular powder.

Applicant: Unimed Healthcare (Pty) Ltd

Module 1.5.5.4

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Holder of Certificate of Registration

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