

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

**Amoxicillin 500mg
Capsules**

(amoxicillin)

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you (or for your child) only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4

In this leaflet:

1. What Amoxicillin Capsules are and what they are used for
2. What you need to know before you take Amoxicillin Capsules
3. How to take Amoxicillin Capsules
4. Possible side effects
5. How to store Amoxicillin Capsule
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1. WHAT AMOXICILLIN CAPSULES ARE AND WHAT THEY ARE USED FOR

Amoxicillin Capsules contain amoxicillin as the active ingredient which belongs to a class of antibiotics called 'penicillins'. Amoxicillin Capsules are used to treat infections caused by bacteria in different parts of the body. Amoxicillin capsules may also be used in combination with other medicines to treat stomach ulcers.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AMOXICILLIN CAPSULES

Do not take Amoxicillin Capsules

- if you are allergic to amoxicillin, penicillin or any of the other ingredients of this medicine (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 Do not take Amoxicillin if any of the above apply. If you are not sure, talk to your doctor or pharmacist before taking amoxicillin.

Warnings and precautions

Talk to your doctor or pharmacist before taking Amoxicillin Capsules if you:

- suffer from kidney problems, since you may need a lower dose.
- have glandular fever (fever, sore throat, swollen glands and extreme tiredness), lymphatic leukemia or HIV infection, since you may be more prone to developing a skin rash.
- are not urinating regularly

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Amoxicillin.

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 the baby is developing normally)

Tell your doctor or pharmacist that you are taking Amoxicillin. This is because Amoxicillin can affect the results of these tests.

Other medicines and Amoxicillin Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- If you are taking allopurinol (used for gout) with Amoxicillin, it may be more likely that you will have an allergic skin reaction.
- If you are taking probenecid (used for gout), your doctor may decide to adjust the dose of Amoxicillin.
- If you are taking medicines to help stop blood clots (such as warfarin), you may need extra blood tests.
- If you are taking other antibiotics (such as tetracycline) Amoxicillin may be less effective.
- If you are taking methotrexate (used for the treatment of cancer and severe psoriasis) Amoxicillin may cause an increase in side effects.

Amoxicillin Capsules with food and drink

These capsules may be taken before, during or after your meals.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Amoxicillin passes into breast milk, so tell your doctor if you are breast-feeding. Ask your doctor for advice before taking any medicine.

Driving and using machines

Amoxicillin can have side effects and the symptoms (such as allergic reactions, dizziness and convulsions) may make you unfit to drive. Do not drive or operate machinery unless you are feeling well.

3. HOW TO TAKE AMOXICILLIN CAPSULES

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

- Swallow with water without opening capsule.
- Space the doses evenly during the day, at least 4 hours apart

The usual dose is

Children weighing less than 40kg who are able to swallow Capsules

All doses are worked out depending on the child's body

weight in kilograms.

- Your doctor will advise you how much Amoxicillin capsules you should give to your baby or child.
- Usual dose - 40mg to 90mg for each kilogram of body weight a day, given in two or three divided doses.
- The maximum recommended dose is 100mg for each kilogram of body weight a day.

Adults, elderly patients and children weighing 40 kg or more

The usual dose of Amoxicillin is 250 mg to 500 mg three times a day or 750 mg to 1 g every 12 hours, depending on the severity and type of infection.

- **Severe infections:** 750 mg to 1 g three times a day
- **Urinary tract infection:** 3 g twice daily for one day.
- **Lyme disease (an infection spread by parasites called ticks):** Isolated erythema migrans (early stage - red or pink circular rash): 4 g a day, Systemic manifestations (late stage - for more serious symptoms or when the disease spreads around your body): up to 6 g a day.
- **Stomach ulcers:** one 750 mg or one 1 g dose twice a day for 7 days with other antibiotics and medicines to treat stomach ulcers.
- **To prevent heart infection during surgery:** the dose will vary according to the type of surgery. Other medicines may also be given at the same time. Your doctor, pharmacist or nurse can give you more details.
- The maximum recommended dose is 6 g per day.

Kidney problems

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

If you take more Amoxicillin Capsules than you should

If you have taken too much Amoxicillin capsules, signs might be an upset stomach (feeling sick, being sick or diarrhoea) or crystals in the urine, which may be seen as cloudy urine, or problems urinating. Talk to your doctor as soon as possible. Take the medicine to show the doctor.

If you forget to take Amoxicillin Capsules

If you miss a dose, take it as soon as you remember and carry on as before. If it is almost time for your next dose, skip the missed dose and continue as usual. Do not take a double dose to make up for a forgotten dose.

How long should you take amoxicillin for?

- Keep taking amoxicillin until the treatment is finished, even you feel better. You need every dose to help fight the infection. If some bacteria survive they can cause the infection to come back. Treatment should be continued for 2 to 3 days after symptoms have gone.
- Once you finish treatment, if you still feel unwell you should go back to see the doctor.

Thrush (a yeast infection of moist areas of the body which can cause soreness, itching and white discharge) may develop if Amoxicillin is used for a long time. If this occurs tell your doctor.

If you take Amoxicillin for a long time, your doctor may perform additional tests to check your kidneys, liver and blood are working normally.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Amoxicillin Capsules can cause side effects, although not everyone gets them.

Stop taking Amoxicillin capsules and see a doctor straight away, if you notice any of the following serious side effects - you may need urgent medical treatment:

The following are very rare (may affect up to 1 in 10,000 people)

- allergic reactions, the signs may include: skin itching or rash, swelling of the face, lips tongue, body or breathing difficulties. These can be serious and occasionally deaths have occurred
- Rash or pinpoint flat red round spots under the skin surface or bruising of the skin. This is due to an inflammation of blood vessel walls due to an allergic reaction. It can be associated with joint pain (arthritis) and kidney problems.
- A delayed allergic reaction can occur usually 7 to 12 days after having amoxicillin, some signs include: rashes, fever, joint pain and enlargement of lymph nodes especially under the arms
- A skin reaction known as 'erythema multiforme' where you may develop: itchy reddish purple patches on the skin especially on the palms of the hands or soles of the feet, 'hive-like' raised swollen areas on the skin, tender areas on the surfaces of the mouth, eyes and genitals. 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.
- 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
- 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)).
the *Jarisch- Herxheimer reaction* which occurs during treatment with Amoxicillin for Lyme disease and cause fever, chills, headache, muscle pain and skin rash.
- inflammation of the large bowel (colon) with diarrhoea (sometimes containing blood), pain and fever
- serious liver side effects may occur. They are mainly associated with people having treatment over a long period, males and the elderly. You must tell your doctor urgently if you get:
 - severe diarrhoea with bleeding
 - blisters, redness or bruising of the skin
 - darker urine or paler stools
 - yellowing of the skin or the whites of the eyes (jaundice). See also anaemia below which might result in jaundice.

These can happen when having the medicine or for up to several weeks after.

If any of the above happens stop taking the medicine and see your doctor straight away.

Sometimes you may get less severe skin reactions such as:

- a mildly itchy rash (round, pink-red patches), 'hive-like' swollen areas on forearms, legs, palms, hands or feet. This is uncommon (may affect up to 1 in 100 people).

If you have any of these talk to your doctor as Amoxicillin will need to be stopped.

The other possible side effects are:

Common (may affect up to 1 in 10 people)

- skin rash
- feeling sick (nausea)
- diarrhoea

Uncommon (may affect up to 1 in 100 people)

- being sick (vomiting).

Very rare (may affect up to 1 in 10,000 people)

- thrush (a yeast infection of the vagina, mouth or skin folds), you can get treatment for thrush from your doctor or pharmacist
- kidney problems
- fits (convulsions), seen in patients on high doses or with kidney problems

- dizziness
- hyperactivity
- crystals in the urine, which may be seen as cloudy urine, or difficulty or discomfort in passing urine. Make sure you drink plenty of fluids to reduce the chance of these symptoms.
- the tongue may change to yellow, brown or black and it may have a hairy appearance.
- an excessive breakdown of red blood cells causing a type of anaemia.
Signs include: tiredness, headaches, shortness of breath, looking pale and yellowing of the skin and the whites of the eyes.
- low number of white blood cells
- low number of cells involved with blood clotting
- the blood may take longer to clot than it normally would. You may notice this if you have a nosebleed or cut yourself.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the manufacturer via the contact provided in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE AMOXICILLIN CAPSULES

Keep this medicine out of the sight and reach of children.

Do not store above 30°C. Store the capsules in their original package and keep containers tightly closed.

Use Amoxicillin Capsules before the expiry date shown on the label. The expiry date refers to the last day of that month.

Do not use this medicine if there are visible signs of deterioration. Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Amoxicillin Capsules contain

The **active** substance is amoxicillin trihydrate each 500 mg capsule contains 500 mg amoxicillin trihydrate.

The **other** ingredients are magnesium stearate maize starch, purified talc

What Amoxicillin Capsules look like and contents of the pack

White to off-white granular powder filled in hard gelatine capsule of shells size '0'. The capsule is a Marooned Cap / Yellow Body embossed with AYRTON AMOXY 500.

The product is available in blister strips of 10 capsules packed as 100 strips per pack

Marketing Authorisation

Holder:

ARYTON DRUG MANUFACTURING LIMITED
Address: P.O. BOX 2149 ACCRA.
Country: GHANA
Telephone: 0302 245090/226761
Telefax: 0302 241804
E-Mail: info@ayrtondrugs.com

Manufacturers:

GR INDUSTRIES

15/5 Valco Road Tema Industrial Area.

ACCRA-GHANA

7. FDA Medicinal Product Registration Number

FDA/SD.04-4119

8. Date of First Registration /Most Current Re-Registration-Date for most current re-registration:

3 December 2019

9. Date of Revision of the Text

June 2020