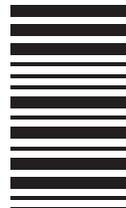


Amoxicillin 250mg Capsules
Amoxicillin 500mg Capsules
(amoxicillin trihydrate)
P1505165



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PACKAGE LEAFLET: INFORMATION FOR THE USER

Amoxicillin 250mg Capsules Amoxicillin 500mg Capsules (amoxicillin trihydrate)

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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What Amoxicillin Capsules are and what they are used for
2. Before you take Amoxicillin Capsules
3. How to take Amoxicillin Capsules
4. Possible side effects
5. How to store Amoxicillin Capsules
6. Further information

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'. The capsules are used to treat infections caused by bacteria that are susceptible to amoxicillin. These include: bronchitis, pneumonia, middle ear, gynaecological, urinary tract, skin (e.g. cellulitis), meningitis, typhoid, dental abscess, blood poisoning, heart inflammation.

2. BEFORE YOU TAKE AMOXICILLIN CAPSULES

Do not take Amoxicillin Capsules if you have:

- an allergy (hypersensitivity) to any penicillin-type antibiotic, or any of the ingredients in the product (*see Section 6*)
- glandular fever.

Take special care with Amoxicillin Capsules

Tell your doctor before taking Amoxicillin Capsules if you:

- suffer from kidney problems, since you may need a lower dose.
- have glandular fever, lymphatic leukaemia or HIV infection, since you may be more prone to developing a skin rash.

Taking other medicines

Please inform your doctor if you are taking or have recently taken any other medicines, including those obtained without a prescription. In particular, tell your doctor if you are taking:

- anticoagulants (used to thin the blood) such as warfarin or phenindione
- probenecid (used to treat gout).
- allopurinol (used to treat gout).

Amoxicillin Capsules may reduce the effectiveness of the oral contraceptive pill, and you should therefore take extra precautions e.g. use a condom during your amoxicillin treatment.

Taking Amoxicillin Capsules with food and drink

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

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicines if you are pregnant or planning to become pregnant. Amoxicillin passes into breast milk, so tell your doctor if you are breast-feeding.

Driving and using machines

Amoxicillin Capsules are not expected to affect your ability to drive or operate machinery.

3. HOW TO TAKE AMOXICILLIN CAPSULES

Amoxicillin Capsules should be swallowed with water.

Your doctor will decide on the appropriate dose to suit the severity and type of infection you have. Always read the label.

Adults and children weighing more than 40kg: The usual dose is 250mg 500mg every 8hours.

Children's:

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.

Elderly and those with kidney problem: The dose may need to be reduced. Your doctor may decide to prescribe Amoxicillin Oral Suspension 125mg/5ml or 250mg/5ml if you need a lower dose.

It is important that you complete the full course of your antibiotics otherwise your infection may come back.

If you take more Amoxicillin Capsules than you should

If you or someone else swallows several of these capsules together, contact your doctor or hospital emergency department immediately. Take the box or any capsules that are left over with you, if you can.

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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.

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

4. POSSIBLE SIDE EFFECTS

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

You may suffer an allergic reaction, symptoms of which include rash, itching, difficulty in breathing, swelling of the face, lips, throat or tongue.

If this happens to you, **stop taking the capsules and consult your doctor immediately.**

You may experience the following:

- 1 General allergic reactions.
 - o Skin reactions are most common, such as rash, hives and pruritus (itch). If you develop any form of skin reaction whilst taking Amoxicillin Capsules, stop taking them and consult your doctor.
 - o Rarer allergic reactions include serum-sickness-like reactions (blistering of the skin and /or mucous membranes of the lips, eyes, mouth, nasal passages or genitals (Stevens-Johnson syndrome) or peeling of the skin (toxic epidermal necrolysis), swollen glands, fluid retention, joint pain, fever, tiredness), haemolytic anaemia (characterised by paleness, shortness of breath, headache, dizziness, tiredness) and kidney inflammation.
- 2 Nausea, vomiting, diarrhoea, colitis (inflammation of the colon).
- 3 Disturbance of liver enzymes. Hepatitis (inflammation of the liver) and jaundice (yellowing of the skin and whites of the eyes) have been reported rarely.
- 4 Paraesthesia (numbness), dizziness.
- 5 Blood disorders, leading to increased risk of infection and bruising as well as anaemia.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE AMOXICILLIN CAPSULES

Keep out of the reach and sight of children.

Do not store above 25°C.

Store the capsules in their original package and keep containers tightly closed.

Use Amoxicillin Capsules before the expiry date shown on the label.

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. FURTHER INFORMATION

What Amoxicillin Capsules contain

The **active** substance is amoxicillin trihydrate

each 250mg capsule contains 250mg amoxicillin trihydrate.

each 500mg capsule contains 500mg amoxicillin trihydrate.

The **other** ingredients are magnesium stearate (E572), colloidal anhydrous silica, titanium dioxide (E171), iron oxides red (E172), iron oxides yellow (E172), erythrosine (E127), indigo-carmin (E132) and gelatin. The ink is composed of shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonia solution, potassium hydroxide, black iron oxide (E172).

What Amoxicillin Capsules look like and contents of the pack

Amoxicillin 250mg Capsules are hard gelatin capsule filled with an off-white powder, with gold body, printed with '250' in black and red cap, printed with "AMOXY" in black.

Amoxicillin 500mg Capsules are hard gelatin capsule filled with an off-white powder, with gold body, printed with '500' in black and red cap, printed with "AMOXY" in black.

Both products are available in container packs of 15, 20, 21, 100, 500 and 1000 capsules as well as blister strips of 15 and 21 capsules (not all pack sizes may be marketed).

Amoxicillin 250mg Capsules are also available in container pack of 50 capsules.

Marketing Authorisation Holder:

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Ares, Odyssey Business Park
West End Road
South Ruislip, HA4 6QD
United Kingdom

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