

PACKAGE LEAFLET: INFORMATION FOR THE USER

Amoxicillin 250mg & 500 mg 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 is usually prescribed for adults and for children who are able to swallow capsules. 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 or pharmacist.

In this leaflet:

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1. WHAT AMOXICILLIN CAPSULES IS AND WHAT IT IS USED FOR

What Amoxicillin Capsule is

Amoxicillin Capsules 250 mg and 500 mg are antibiotics. The capsules contain a medicine called amoxicillin. This belongs to a group of medicines called 'penicillins'.

What Amoxicillin Capsule is used for

Amoxicillin Capsule is used to treat infections in different parts of the body caused by bacteria. It is also used to stop infections when you have a tooth removed or other surgery. Amoxicillin Capsule may also be used in combination with other medicines to treat stomach ulcers.

2. BEFORE YOU TAKE AMOXICILLIN CAPSULES

Do not take Amoxicillin capsule if you:

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

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

Take Special Care with Amoxicillin Capsules

Check with your doctor or pharmacist before taking this medicine if you:

- have glandular fever
- are being treated for kidney problems
- are not passing water regularly.
- If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Amoxicillin Capsules.

Having urine or blood tests

If you are having tests on your water (urine glucose test) or blood tests for liver function, let the doctor or nurse know that you are on Amoxicillin Capsule. This is because Amoxicillin Capsule can affect results of these tests.

Taking other medicines

Please tell your doctor or pharmacist if you taking or have recently taken any other medicines. This includes medicines that can be bought without a prescription and herbal medicines. This is because Amoxicillin Capsules can affect the way some other medicines work. Also some other medicines can affect the way Amoxicillin Capsules works.

- If you are taking allopurinol (used for gout) with Amoxicillin Capsules, it may be more likely that you'll have an allergic skin reaction.
- If you are taking probenecid (used for gout), your doctor may decide to adjust your dose of Amoxicillin Capsules.
- If medicines to help stop blood clots (such as warfarin) are taken with Amoxicillin Capsules then extra blood tests may be needed. Amoxicillin Capsules may stop the contraceptive pill working. You will need to use extra contraceptive precautions, such as using a condom. If you need any advice, talk to your doctor or pharmacist.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine if you think you might be or if you are pregnant, or if you are breast-feeding.

3. HOW TO TAKE AMOXICILLIN CAPSULES

Always take Amoxicillin Capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

When taking Amoxicillin Capsules

- Swallow the capsules whole with a glass of water at the start of a meal or slightly before
- Space the doses evenly during the day, at least 4 hours apart
- Never take 2 doses in 1 hour
- The maximum recommended dose is 6 g per day given as 2 × 3 g doses.

The usual dose is:

Children weighing less than 40 kg 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 40 mg to 90 mg for each kilogram of body weight a day, given in two or three divided doses.

Adults, elderly patients and children weighing more than 40 kg

- **Standard dose:** 1 × 250 mg capsule 3 times a day.
- **Severe infections:** 1 × 500 mg capsule 3 times a day.
- **Severe or recurrent chest infection:** 3 g (6 × 500 mg capsules) twice a day
- **Urinary tract (water) infection:** 2 × 3 g doses (6 × 500 mg capsules) with 10 - 12 hours between each dose.
- **Dental abscess (infection under the gums and teeth):** 2 × 3 g doses (6 × 500 mg capsules) with 8 hours between each dose.
- **Gonorrhoea (a sexually transmitted infection):** 1 × 3 g doses (6 × 500 mg capsules).
- **Stomach ulcers:** 1 × 750 mg dose (3 × 250 mg capsules or 1 × 500 mg capsules and 1 × 250 mg capsule) or 1 × 1 g dose (2 × 500 mg capsule) twice a day for 7 days with other antibiotics.

To stop 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.

Kidney problems

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

If you take too much Amoxicillin Capsules

If you take 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 passing urine. Talk to your doctor as soon as possible. Take the medicine to show the doctor.

If you forget to take Amoxicillin Capsules

- If you forget to take a dose don't worry, take it as soon as you remember.
- Don't take the next dose too soon, wait about 4 hours before taking the next dose.

How long should you take Amoxicillin Capsules for?

- Keep taking Amoxicillin Capsules until the treatment is finished, even if 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 the symptoms have gone.
- Do not take Amoxicillin Capsules for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

Thrush (a yeast infection of moist areas of the body) may develop if Amoxicillin Capsules is used for a long time. If this occurs and you have been taking Amoxicillin Capsules for longer than recommended, tell your doctor.

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 everybody gets them. The following side effects may happen with the medicine.

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 (affects less than 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 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 Capsules, some signs include: rashes, fever, joint pains and enlargement of the 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 private parts. 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
- high temperature (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
- inflammation of the large bowel (colon) with diarrhoea sometimes containing blood, pain and fever
- serious liver side effects may occur which are often reversible. They are mainly associated with people having treatment over a long period, males and the elderly. You must tell 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 medicines or for up to several weeks after.

Sometimes you may get less severe skin reactions such as:

- a middle itchy rash (round, pink-red patches), 'hive-like' swollen areas on forearms, legs, palms, hands or feet. This is uncommon (affects less than 1 in 1000 people).

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

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

The other possible side effects are:

Common (affects less than 1 in 10 people)

- skin rash
- feeling sick (nausea)
- diarrhoea.

Uncommon (affects less than 1 in 100 people)

- being sick (vomiting).

Very rare (affects less than 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 chances of these symptoms
 - teeth may appear stained, usually returning to normal with brushing (this has been reported in children)
 - 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 form of anaemia. Signs include: tiredness, headaches, shortness of breath, dizziness, looking pale and yellowing of the skin and the whites of the eyes
 - the blood may take longer to clot than it normally would. You may notice this if you have a nosebleed or cut yourself.
- 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 use Amoxicillin Capsules after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Store in the original pack below 30°C.
- Do not use Amoxicillin Capsules 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. FURTHER INFORMATION

What Amoxicillin Capsules contains

- The active substance is each capsule is 250 mg or 500 mg Amoxicillin Trihydrate.
- The other ingredients are Croscarmellose Sodium, Magnesium stearate, Sunset yellow E110, Carmosine E122, Brilliant blue E133, Quinoline Yellow E 104, Titanium dioxide E171, Methyl parahydroxybenzoate and Propyl parahydroxybenzoate.

What Amoxicillin Capsules looks like and contents of the pack

Red / Buff coloured capsules printed with 'AMOXY 250' in black ink.
Red / Buff coloured capsules printed with 'AMOXY 500' in black ink.

Amoxicillin 250mg and 500mg are supplied in pack sizes of 21, 100 & 500. Not all packs sizes may be marketed.

Marketing Authorization Holder and Manufacturer

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