

PATIENT INFORMATION LEAFLET

OMACILLIN 250MG / 500MG CAPSULES

Amoxycillin trihydrate



Please read this leaflet carefully before you start to take your medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should 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 get serious, or if you notice any side effects not listed in the leaflet, please tell your doctor or pharmacist.

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1. WHAT OMACILLIN IS AND WHAT IT IS USED FOR :

Amoxycillin is one of a group of antibiotic medicines called penicillins. Amoxycillin works by interfering with the bacteria that cause the infection.

Amoxycillin can treat a wide range of infections including those of the following:

- Chest (bronchitis or pneumonia) skin
- Tonsils (tonsillitis) bone
- Ears (otitis media) teeth
- Sinuses (sinusitis) heart (endocarditis)
- Kidneys gums (abscesses)
- Blood (septicaemia)
- Abdomen (intra-abdominal sepsis and peritonitis)
- The bladder or the urethra (the tube which carries urine from the bladder)
- The female reproductive system including infections caused by difficulties during childbirth (puerperal sepsis and septic abortion).

Amoxycillin can also be used to treat:

- Gonorrhoea (a sexually transmitted infection)
 - Infections associated with pregnancy
 - Typhoid and paratyphoid (fevers caused by a group of bacteria called Salmonella).
- Amoxycillin may also be used in combination with other medicines to treat stomach ulcers.

2. BEFORE YOU TAKE OMACILLIN :

Do not take this medicine and consult your doctor if the answer to any of the following is yes:

- You have ever had a bad reaction or allergy to any penicillin-type antibiotic.
- You have ever had a skin rash or swelling of the face or neck or shortness of breath when taking any antibiotic.
- You are allergic to any of the ingredients contained in this medicine.

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

- You suffer from kidney disease or kidney problems, as you may require a lower dose than normal.
- You have glandular fever.

Taking other medicines :

Check with your doctor or pharmacist if you are taking, or have recently taken any other medicines even those not prescribed by a doctor. In particular tell your doctor if you are taking any of the following:

- The contraceptive pill (in which case you will have to take extra contraceptive measures such as using a condom).
- Anticoagulants e.g. warfarin, phenindione
- Chemotherapy drugs e.g. methotrexate
- Drugs used to treat gout (which can be caused by the build up of uric acid) e.g. probenecid, allopurinol, sulfinpyrazone.
- Some other antibiotics (e.g. neomycin and tetracyclines can reduce the effect of Amoxycillin).
- Oral typhoid vaccine (may not work if taken with Amoxycillin).
- Some penicillins may increase the effects of muscle-relaxing drugs given as part of an anaesthetic for surgery.

Tell the doctor you are taking Amoxycillin if you need to have an anaesthetic.

Having urine or blood tests :

If you are having urine tests for diabetes (sugar in the urine) or blood tests for liver function let the doctor know. Amoxycillin can affect the results of these tests.

Pregnancy and breast-feeding :

Check with your doctor before you take this medicine if you are pregnant or breast-feeding.

3. HOW TO TAKE OMACILLIN :

Follow all directions given to you by your doctor or pharmacist. Their directions may differ from the information contained in this leaflet. Your doctor may advise you to take your medicine in a different way, so you should always follow your doctor's advice about when and how to take your medicine and always read the label. Your pharmacist may be able to help if you are not sure.

The maximum daily dose is 6g given in divided doses.

Adults including the elderly :

The usual dose of Amoxycillin Capsules is 250mg three times a day.

- For more severe infections this may be doubled to 500mg three times a day.
- High doses may be used in the following conditions:
 - For severe or recurrent chest infections a dose of 3g twice daily given orally is usually recommended.
 - For simple urinary tract infections an adult dose of two 3g doses given orally with 10 to 12 hours between doses (short course).
 - For the treatment of dental abscesses two 3g doses given orally with 8 hours between doses is recommended.
 - For gonorrhoea a single 3g dose given orally is recommended.
 - For stomach ulcers, the following may be prescribed with other antibiotics: 1 x 750mg or 1 x 1g twice a day for 7 days.

The following are the usual adult dosages for preventing infection during dental procedures and other surgery :

- If a general anaesthetic is not used, 3g given orally one hour before surgery and another dose six hours later if necessary.
- If a general anaesthetic is used, 3g given orally four hours before anaesthesia and 3g six hours after the initial dose.

Children :

It is recommended that children be given Amoxycillin as a suspension instead of as capsules.

- Children weighing more than 40kg should be given the usual adult dosage.
- 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 medicine you should give to your baby or child.

The usual dose is 40mg to 90mg for each kilogram of body weight a day, given in two or three divided doses.

Patients with kidney problems :

If you have kidney problems, the dose prescribed by your doctor may be lower than the usual dose.

When to take Omacillin :

Try to give/take this medicine as part of the daily routine, for example at mealtimes. You may give/take Amoxycillin before, with or after food, unless the label advises a specific time. It is not normally necessary to arrange to have a dose in the middle of the night, unless your doctor has told you to do so. But remember, space the doses as evenly as possible throughout the day.

Do not give/take more than one dose every four hours.

If you forget to take Omacillin :

If you forget to take a dose, take it as soon as you remember, unless it is within an hour of your next dose, then carry on as before. Do not take a double dose to make up for the dose you have missed.

If you take more of Omacillin than you should :

If you take more capsules than you should, tell your doctor immediately or go to the nearest hospital. You should take this leaflet and any capsules you still have to show the doctor.

Severe cases of nausea, vomiting and diarrhoea can be treated with rehydration therapy, by drinking fluids containing sodium, water and sugar to prevent dehydration.

REMEMBER :

Keep taking this medicine until it is finished or your doctor tells you to stop. Do not stop taking it just because you feel better. If you stop taking the medicine, some bacteria may survive and cause the infection to come back, or your condition may re-occur or get worse.

You should make sure you have several more drinks of water each day unless told otherwise by your doctor.

If you are still unwell after taking all the medicine, go and see your doctor. Never give/ take more than the recommended dose each day.

4. POSSIBLE SIDE EFFECTS :

As with all medicines, some people may experience side effects with Amoxycillin.

If you experience any of the following events STOP taking your medicine and tell your doctor or go to your nearest hospital immediately:

- Hypersensitivity or severe allergic reaction including swollen face or breathing problems. If these symptoms occur, STOP taking Amoxycillin right away and tell your doctor.
- Severe diarrhoea with bleeding.
- Allergic skin reactions with itching e.g. hives, nettle rash, blistering or peeling of the skin. If you start to itch or get a rash, STOP taking Amoxycillin and tell your doctor immediately.
- Convulsions may occur in patients on high doses or with kidney problems.
- Notice your urine becoming darker or your faeces becoming paler.
- Notice your skin or the white of your eyes turning yellow (jaundice).
- Difficulty or discomfort in passing urine or having cloudy urine.

The following symptoms are less serious but you may wish to discuss them with your doctor if they become troublesome or last a long time.

Common side effects of Amoxycillin (i.e. have been reported in more than 1 in 100 people taking it) include:

- Nausea (feeling sick) or diarrhoea

Uncommon side effects : (i.e. have been reported in between 1 in 100 and 1 in 1,000 people taking Amoxycillin) include:

- Vomiting

Very rare side effects : (i.e. reported in less than 1 in 10,000 people) include:

- Thrush (a yeast infection of the vagina, mouth or skin folds). You can get treatment for thrush from your doctor or pharmacist.
 - Tooth discolouration. The colour usually returns to normal with brushing.
 - Blackening of the tongue
 - Inflammation of the kidney
 - Excessive body movements (hyperkinesia) or dizziness.
 - Reduction (reversible) in blood cell counts including anaemia (a reduction in the body's red blood cells or haemoglobin which may be characterised by feeling weak or light-headed) or a longer time taken for blood to clot. Tell your doctor that you are taking Amoxycillin if you are having blood tests.
 - Crystalluria, forming of crystals in the urine.
- If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE OMACILLIN :

Keep this out of reach of children.

Store below 30°C. Protect from light & moisture.

6. FURTHER INFORMATION :**What Amoxycillin capsules contain :**

Each capsule contains 250 mg or 500 mg of Amoxycillin as Amoxycillin trihydrate.

Other Ingredients: Sodium starch Glycolate, Sodium lauryl sulphate, Magnesium stearate, Talc, Empty hard gelatin capsule.

What Amoxycillin capsules look like and contents of the pack :

Omacillin 250 mg capsules: Hard gelatin capsule with yellow body having 'Omacillin 250mg' printed in black colour and red cap with 'NPI' logo printed in white colour contains off-white to yellow powder.

Omacillin 500 mg capsules: Hard gelatin capsule with yellow body having 'Omacillin 500mg' printed in black colour and red cap with 'NPI' logo printed in white colour contains off-white to yellow powder.

Pack : Blister of 10 capsules.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instruction is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instruction of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep all medicament out of the reach of children.
Council of Arab Health Ministers,
Union of Arab Pharmacists.

Manufactured by

National Pharmaceutical Industries Co. (SAOG)
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Muscat, Sultanate of Oman.

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