

## PATIENT INFORMATION LEAFLET

# AMOXICILLIN 250mg/500mg CAPSULES

### What is Amoxicillin 250/500mg Capsules and what is it used for?

The name of your medicine is Amoxicillin 250mg capsules or Amoxicillin 500mg capsules.

**250mg Capsules:** Each capsule contains 250mg of Amoxicillin as the active ingredient. Each capsule is size '2', ivory/scarlet hard gelatin capsule. In addition, the capsules contain magnesium stearate.

**500mg Capsules:** Each capsule contains 500mg of Amoxicillin as the active ingredient. Each capsule is size '0', ivory/scarlet hard gelatin capsule. In addition, the capsules contain magnesium stearate.

The capsule shell is made of gelatin and contains the following colouring agents: E110 Sunset yellow, E127 Erythrosine, E131 Patent Blue, E171 Titanium dioxide. Amoxicillin capsules come in containers of 100, 500 and 1000 capsules.

Amoxicillin is an antibiotic. It works by killing bacteria that cause some types of infections. Amoxicillin belongs to a group of antibiotics called penicillins.

Amoxicillin 250/500mg Capsules are used to treat a range of bacterial infections including those of the

- chest (bronchitis or pneumonia)
- ears
- sinuses
- throat
- kidneys and bladder
- gut and areas around the gut

They may also be used to help prevent infections of the heart valves that may follow some surgical and dental operations in patients who have a particular risk of developing such infections.

### Who makes your Amoxicillin 250/500mg Capsules?

The product Licence Holder of Amoxicillin Capsules is Mobius Healthcare Ltd, Unit 7 Bourne End Mills, Upper Bourne End Lane, Hertfordshire, HP1 2UJ, UK.

### Before you take Amoxicillin 250/500mg Capsules

Do not take Amoxicillin 250/500mg Capsules if any of the following apply to you

- If you think you are, or you have been told you are, sensitive or allergic to penicillin, amoxicillin or to certain other antibiotics such as cephalosporins.
- You have a viral infection, including a viral infection called infectious mononucleosis or glandular fever
- You have blood disease called acute lymphatic leukaemia

Amoxicillin 250/500mg Capsules may or may not be suitable for you if any of the following apply. If you are not sure, discuss these with your doctor or pharmacist before you take Amoxicillin 250/500mg Capsules. Make sure that you tell your doctor about all medicines that you are taking, whether or not these are prescribed or have been bought over the counter.

- If you are suffering from diarrhoea and vomiting. This may reduce the effect of your medicine
- If you have asthma
- If you suffer from any allergies
- If you have any problems with your kidneys or have a catheter to enable you to pass urine
- If you are having blood or urine tests for sugar or a substance found in bile called urobilinogen because false positive results may occur. If you are diabetic, it is important that you know that Amoxicillin 250/500mg Capsules can affect the results of certain glucose tests.
- If you are pregnant, the levels of a hormone called oestriol in your urine may fall. It is important that your doctor and midwife know that you are taking amoxicillin so that they can interpret the test results correctly.
- In premature children and during the neonatal period: renal, hepatic and haematological functions should be monitored.
- **Amoxicillin capsules contain Sunset Yellow. This may cause allergic reactions.**

### Breast feeding and pregnancy

If you are pregnant, think you may be pregnant or are planning become pregnant, discuss this with your doctor for advice before taking any medicine. Small amounts of amoxicillin may enter the breast milk and can occasionally cause diarrhoea or mouth infections in infants. Infants may also become allergic to amoxicillin. If you are breastfeeding, discuss this with your doctor before you take Amoxicillin 250/500mg Capsules.

### Taking other medicines

Amoxicillin 250/500mg Capsules are not recommended for use with some other medicines and special care is needed when it is given with others. Make sure that you will tell your doctor about all medicines that you are taking, whether

or not these are prescribed or have been bought over the counter. Amoxicillin 250/500mg Capsules may or may not be suitable for you if:

- You are taking allopurinol (a medicine for gout) because the risk of allergic skin rashes is increased
- You are taking probenecid because this can cause the blood concentrations of amoxicillin to increase
- You are taking digoxin (a heart medicine) because blood concentrations of this drug may increase
- You are taking warfarin or any other medicine that prevents blood clotting because the time it takes for your blood to clot may be even longer while you are taking amoxicillin and you may need extra blood tests because of this
- You are taking certain other antibiotics called macrolides, tetracyclines, chloramphenicol, or sulphonamides because the effect of amoxicillin may be reduced
- You are taking the contraceptive pill. Amoxicillin 250/500mg Capsules may reduce the effect of the pill. You should therefore take additional contraceptive precautions such as using a condom or diaphragm with a spermicide

#### **How to take Amoxicillin 250/500mg Capsules**

You should always take this medicine as prescribed by your doctor. Do not take more than the doctor told you to. Follow the instructions on the pharmacist's label. If you are not sure about anything please ask your doctor or pharmacist.

The dose you are prescribed will depend on the type and severity of your infection. The usual dose for adults and adolescents (13 years or more) weighing over 40kg is one 250mg capsule three times a day. For more severe infections your doctor may prescribe a higher total daily dose.

In simple bladder infections (cystitis), you may be instructed to take only two doses 12 hours apart to treat the infection. Each dose is usually of 3g.

If you are given amoxicillin because you have a risk of developing an infection of the heart valves during a surgical or dental procedure and you are not having a general anaesthetic, you would usually be given 3g within one hour of the start of the procedure and, possibly, another dose of 3g about 6 hours later.

Amoxicillin 250/500mg Capsules are not recommended for children (under 13 years) or those weighing less than 40kg. In order to give the right dose, other size capsules, tablets and suspensions containing amoxicillin are available for these persons as below.

#### **Children:**

Children weighing less than 40 kg

The daily dosage for children is 40-90 mg/kg/day in two to three divided doses (not exceeding 3 g/day) depending on the indication, severity of the disease and the susceptibility of the pathogen

Dosing three times daily is associated with enhanced efficacy, thus twice daily dosing is only recommended when the dose is in the upper range.

Children weighing more than 40 kg should be given the usual adult dosage.

#### **Other dosages which may be given are:**

Tonsillitis: 50 mg/kg/day in two divided doses.

Acute otitis media: In areas with high prevalence of pneumococci with reduced susceptibility to penicillins, dosage regimens should be guided by national/local recommendations.

Early Lyme disease (isolated erythema migrans): 50 mg/kg/day in three divided doses, over 14-21 days.

Prophylaxis for endocarditis: 50 mg amoxicillin/kg body weight given as a single dose one hour preceding the surgical procedure.

Impaired renal function: The dose should be reduced. In patients with a creatinine clearance of less than 30 ml/min an increase in the dosage interval and a reduction in the total daily dose is recommended

If you have kidney problems your doctor may decide to give you lower dose.

Swallow the capsules with drink e.g. water. Do not chew the capsules. The capsules can be taken before, with or after food. Space the doses as evenly as possible throughout the day.

Your doctor will tell you how long your treatment with Amoxicillin 250/500mg Capsules will last. Treatment is usually continued for two or three days after the symptoms of the infection have disappeared.

It is important that you keep taking Amoxicillin 250/500mg Capsules until the prescribed course is finished. Do not stop taking the capsules just because you feel better. If you stop too soon, the infection may start up again.

If you still feel unwell at the end of your prescribed course of treatment, or feel worse during treatment, tell your doctor.

If you forget to take Amoxicillin 250/500mg Capsules at the right time, take it as soon as you remember. Do not take a double dose to make up for forgotten individual doses.

If you have taken more Amoxicillin 250/500mg Capsules than you should, drink plenty of water and consult your doctor or the nearest hospital casualty department immediately. Take this leaflet or some capsules with you so that people will know what you have taken.

### **Possible side effects**

Like all medicines, Amoxicillin 250/500mg Capsules can have side effects. In this section, common side effects occur in less than one in ten patients but more than one in a hundred. Uncommon side effects occur in less than one in a hundred patients but more than one in a thousand patients.

Rare side effects occur in less than one in a thousand patients but more than one in ten thousand patients. Very rare side effects occur in less than one in ten thousand patients.

Allergic reactions may occur commonly during treatment with amoxicillin but severe allergic reactions are rare. If any of the following happen, stop taking Amoxicillin 250/500mg Capsules and tell your doctor (or an emergency doctor) immediately. You may need urgent medical attention or hospitalisation.

- skin rash, redness or itching; some sort of skin rash may occur commonly.
- swelling of the face or neck. Mild forms occur commonly, but severe forms are rare
- blistering or peeling of the skin, with or without ulceration in the mouth and sore eyes or sore genitals. These are rare side effects.
- In rare cases there may be joint pain and fever, breathing problems, sweating, rapid heart beat or loss of consciousness.

Other rare side effects that may be due to allergy are increases in number of one type of white blood cells called eosinophils, drops in number of red blood cells causing anaemia, inflammation and damage to the blood vessels causing purple spots or blotches in and under the skin, and inflammation of the kidney.

Also, tell your doctor immediately if you experience any of the following rare or very rare possible side effects of treatment because they are, or may be, serious:

- If your skin or the whites of your eyes turn yellow, your urine turns dark or faeces become very pale
- If you have severe diarrhoea, with or without bleeding
- If you have a fit
- If you have abnormal bruising or notice that you bleed for longer after minor wounds
- If you have pain in the area of the kidneys (this will feel like low back pain)

### **Other possible side effects:**

The following have been reported commonly:  
Stomach complaints, loss of appetite, feeling sick, being sick, wind, soft stools, diarrhoea, ulceration of the mouth, dry mouth, and disturbances in taste. These symptoms are usually mild and disappear either during treatment or very soon

after completion of treatment. These symptoms may be reduced by taking the capsules with food. If diarrhoea is severe or you see blood, you should contact your doctor immediately (see above).

Some people develop thrush (a yeast infection of the vagina, mouth or skin folds) whilst they are taking antibiotics. Uncommonly, the blood levels of enzymes made by the liver may be increased.

Rarely, inflammation of the liver, acute inflammation of kidneys, uncontrolled or restless movements of the arms and legs, and dizziness have been reported. Fits have been reported particularly in patients with kidney disorders or if high doses are being taken.

In very rare cases the tongue turn black.

There have been isolated reports of change in the composition of the blood. These include decreases in the number of various different types of white blood cells, decreases in the numbers of red blood cells or platelets or of all types of blood cells. There have also been isolated reports of prolonged bleeding time and an increase in the time taken for blood to clot. These blood changes have returned to normal after stopping treatment.

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

### **Storing Amoxicillin 250/500mg Capsules**

Amoxicillin capsules should be kept out of the reach and sight of children.

Do not store the capsules above 25°C.

Store in the original pack.

If your doctor decides to stop the treatment, return any capsules left over to the pharmacist. Only keep them if your doctor tells you to. Do not use after the expiry date printed on the package.

**Important reminder:** Do not give your capsules to anyone else, even if they suffer from the same condition as you. This medicine could be harmful to them or interfere with other treatments. Your medicine has been prescribed by your doctor specifically for you.

Legal status: POM

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