

# AMOXICILLIN CAPSULES 250 mg & 500 mg

**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 become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## THIS LEAFLET CONTAINS

1. What Amoxicillin is for
2. Before you take Amoxicillin
3. How to take Amoxicillin
4. Possible side effects
5. How to store Amoxicillin
6. Further information

## 1. WHAT AMOXICILLIN IS FOR

The name of your medicine is Amoxicillin. It contains the active ingredient amoxicillin trihydrate. This belongs to a group of antibiotics called penicillins.

Amoxicillin can be used to treat bacterial infections of:

- the respiratory tract (nose, throat and lungs)
- the skin and soft tissue
- the urinary system (bladder and kidneys)
- the female reproductive system
- the ear, nose and throat
- the gums and teeth
- the blood, bone and abdomen.

Amoxicillin can also be used in combination with other medicines to treat stomach ulcers, as well as in patients with heart disease who need protection from infection during dental treatment.

If you are not sure why you have been prescribed this medicine then please ask your doctor.

## 2. BEFORE YOU TAKE AMOXICILLIN

**Do not take Amoxicillin and tell your doctor if you:**

- are allergic to amoxicillin or to any of the other ingredients in the capsules (listed in section 6 of this leaflet)
- are allergic to other penicillin products or to antibiotics known as cephalosporins.

The signs of an allergic reaction can include a rash, itching, shortness of breath or swelling of the face or throat.

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

**Take special care with Amoxicillin**

Tell your **doctor** before you take this medicine if you:

- have kidney problems: your doctor may have to lower your dose
- are not passing urine regularly
- have glandular fever or leukaemia: you may have a higher risk of skin reactions.

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

## Having tests

If you are having blood tests or urine tests to check your sugar levels, tell the doctor that you are taking Amoxicillin as it may interfere with the results.

## Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken **any** other medicines, including medicines bought without a prescription. This is because Amoxicillin can affect the way some medicines work. Also some medicines can affect the way Amoxicillin works.

In particular, tell your doctor or pharmacist if you are taking any of the following:

- Probenecid to treat gout: the levels of amoxicillin may be increased in your blood
- Allopurinol to prevent gout: you may have a higher risk of skin reactions
- Anticoagulants (to prevent blood clotting) such as Warfarin: the tendency to bleed may be increased
- Contraceptive pills: there is a risk of contraceptive pills not working to their greatest effect. An additional form of contraception should be used, such as condoms.

## Taking Amoxicillin with food and drink

It is recommended that you take Amoxicillin at the start of meals to reduce any possible digestive discomfort.

## Pregnancy and breast-feeding

If you are pregnant, planning to become pregnant or are breast-feeding, ask your doctor or pharmacist for advice before taking any medicine.

## Driving and using machines

Amoxicillin should not affect your ability to drive or operate machinery.

## 3. HOW TO TAKE AMOXICILLIN

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

Swallow the capsules whole with a glass of water at the start of a meal.

## Dosage

Your doctor will decide your dose and length of treatment, as it depends on your condition.

## Adults, Elderly and Children over 10 years old:

The usual dose is 250 mg three times a day. For severe infections your doctor may increase your dose to 500 mg three times a day.

## Children under 10 years old:

For severe infections your doctor may give your child 250 mg three times a day.

Oral suspensions containing amoxicillin are recommended for infants, as well as children who cannot swallow capsules.

## People with kidney problems:

Your doctor may have to lower your dose.

## If you take more Amoxicillin than you should

If you take more Amoxicillin than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you so the doctor knows what you have taken. Signs of an overdose may include feeling sick, being sick, diarrhoea or crystals in the urine, which may be seen as cloudy urine, or difficulty in passing urine.

### **If you forget to take Amoxicillin**

If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

### **If you stop taking Amoxicillin**

Keep taking this medicine until the course is finished, even if you feel better. If you stop taking this medicine too soon, the infection may come back.

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 can cause side effects, although not everybody gets them.

**If you notice any of the following serious side effects, STOP TAKING Amoxicillin and see a doctor or go to a hospital straight away:**

**The following are very rare (affects less than 1 in 10, 000 people):**

- allergic reactions, which may cause an itchy skin rash, swelling of the face, lips, tongue or throat, difficulty in breathing, speaking or swallowing, dizziness or collapse
- flat red spots under the skin surface or bruising of the skin. This is due to an allergic reaction caused by inflammation of blood vessel walls
- a delayed allergic reaction which can occur 7 to 14 days after taking this medicine. The signs may include rashes, fever, joint pain or swollen lymph nodes
- itchy reddish purple patches on the skin especially on the palms of the hands or soles of the feet
- other severe skin reactions causing small pus-containing blisters, changes in skin colour, flaky skin, peeling, redness or blistering of the skin, mouth, eyes or genitals. These may be associated with fever, headaches and body aches
- blood disorders, which may cause fever, chills, sore throat, ulcers in the mouth or throat, unexplained bleeding or bruising. Your doctor may wish to test your blood
- inflammation of the large intestine (colitis), which may cause aches and pain in the stomach area, diarrhoea, blood in the stools, tiredness, fever, joint pain or weight loss
- kidney problems, which may cause a change in the amount of urine passed, blood in the urine, swollen ankles, feeling or being sick, or confusion
- liver problems, which may cause yellowing of the skin or whites of the eyes (jaundice), or darker urine or paler stools. These may happen several weeks after you stop taking this medicine.

**If you get any of the following side effects, talk to your doctor as soon as possible:**

**Common (affects less than 1 in 10 people):**

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

**Uncommon (affects less than 1 in 100 people):**

- being sick (vomiting)
- skin itching or red and raised lumps (hives).

**Very rare (affects less than 1 in 10,000 people):**

- abnormal breakdown of red blood cells (haemolytic anaemia), which can make the skin pale yellow and cause tiredness, weakness or breathlessness
- bleeding for longer than usual. You may notice this if you have a nosebleed or cut yourself
- changes in the colour of your teeth. This is usually removed by brushing
- a black "hairy" tongue
- dizziness
- fits (convulsions), seen in patients on high doses or with kidney problems
- feeling unusually excitable (hyperactivity)
- crystals in the urine (crystalluria), which may be seen as cloudy urine, or difficulty in passing urine. Make sure you drink plenty of fluids to reduce the chance of getting these symptoms
- vaginal itching, soreness and discharge due to yeast infections (thrush). Your doctor or pharmacist can give you treatment for thrush.

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

## **5. HOW TO STORE AMOXICILLIN**

**Keep out of the reach and sight of children.**

Store below 25°C in a dry place. Store in the original package or container and keep the container tightly closed.

Do not use this medicine after the expiry date, which is stated on the package or container. The expiry date refers to the last day of that month.

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 (the ingredient that makes the capsules work) is amoxicillin trihydrate. The other ingredients are magnesium stearate, gelatin, titanium dioxide (E171) and red and yellow iron oxides (E172).

### **What Amoxicillin Capsules look like and contents of the pack**

Amoxicillin capsules are maroon and flesh coloured capsules with 'DEDOXIL 250' or 'DEDOXIL 500' printed on them in black ink.

Both strengths come in blister packs and containers of 7, 14, 15, 21, 28, 30, 56, 60, 100 and 500 capsules. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

DDSA Pharmaceuticals Limited,  
310 Old Brompton Road,  
London SW5 9JQ

### **Distributor**

Genesis Pharmaceuticals Limited,  
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For more information about this product, please contact the Marketing Authorisation Holder.

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