

## **Package leaflet: Information for the user**

### **Amoxicillin 250mg Hard Capsules Amoxicillin 500mg Hard Capsules**

amoxicillin

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- 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 (or for your child) only. Do not pass it on to others. It may harm them even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Amoxicillin hard capsules are and what they are used for
2. What you need to know before you take Amoxicillin hard capsules
3. How to take Amoxicillin hard capsules
4. Possible side effects
5. How to store Amoxicillin hard capsules
6. Contents of the pack and other information

#### **1. What Amoxicillin hard capsules are and what they are used for What Amoxicillin hard capsules are**

Amoxicillin hard capsules are antibiotics. The active ingredient is amoxicillin trihydrate. This belongs to a group of medicines called 'penicillins'.

#### **What Amoxicillin hard capsules are used for**

Amoxicillin hard capsules are used to treat infections caused by bacteria in different parts of the body. Amoxicillin hard capsules may also be used in combination with other medicines to treat stomach ulcers.

#### **2. What you need to know before you take Amoxicillin hard capsules**

##### **Do not take Amoxicillin hard capsules:**

- if you are allergic to amoxicillin, penicillin or any of the other ingredients contained in this medicine (listed in section 6).
- if you have ever had an allergic reaction to any antibiotic. This can include a skin rash or swelling of the face or throat.

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

#### **Warnings and Precautions**

Talk to your doctor or pharmacist before taking Amoxicillin hard capsules if you:

- have glandular fever (fever, sore throat, swollen glands and extreme tiredness)
- have kidney problems
- are not urinating regularly

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

### **Blood and urine tests**

If you are having:

- Urine tests (glucose) or blood tests for liver function
- Oestriol tests (used during pregnancy to check the baby is developing normally)

Tell your doctor or pharmacist that you are taking Amoxicillin hard capsules. This is because Amoxicillin hard capsules can affect the results of these tests.

### **Other medicines and Amoxicillin hard capsules**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- If you are taking allopurinol (used for gout) with Amoxicillin hard capsules, it may be more likely that you will have an allergic skin reaction.
- If you are taking probenecid (used for gout), concomitant use of probenecid may reduce the excretion of amoxicillin and is not recommended.
- If you are taking medicines used to stop blood clots (such as warfarin) you may need extra blood tests.
- If you are taking other antibiotics (such as tetracycline) Amoxicillin hard capsules may be less effective.
- If you are taking methotrexate (used for the treatment of cancer and severe psoriasis) Amoxicillin hard capsules may cause an increase in side effects.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### **Driving and using machines**

Amoxicillin hard capsules can have side effects and the symptoms (such as allergic reactions, dizziness and convulsions) may make you unfit to drive.

Do not drive or operate machinery unless you are feeling well.

### **3. How to take Amoxicillin hard capsules**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Swallow with water without opening capsule.
- Space the doses evenly during the day at least 4 hours apart.

The recommended dose is:

#### **Children weighing less than 40 kg**

All doses are worked out depending on your child's body weight in kilograms.

It is recommended that children (younger than 6 years age) be given Amoxicillin as a suspension instead of as capsules.

- Your doctor will advise you how much Amoxicillin hard capsules you should give to your baby or child based on their specific infection.
- The usual dose is 40 mg – 90 mg for each kilogram of body weight a day, given in two or three divided doses.
- The maximum recommended dose is 100 mg for each kilogram of body weight a day.

#### **Adults, elderly patients and children weighing 40 kg or more**

The usual dose of Amoxicillin hard capsules is 250 mg to 500 mg three times a day or 750 mg to 1 g every 12 hours, depending on the severity and type of infection.

- **Severe infections:** 750 mg to 1 g three times a day.
- **Urinary tract infection:** 3 g twice daily for one day.

- **Lyme disease (an infection spread by parasites called ticks):** Isolated erythema migrans (early stage – red or pink circular rash): 4 g a day, Systemic manifestations (late stage – for more serious symptoms or when the disease spreads around your body): up to 6 g a day.
- **Stomach ulcers:** one 750 mg or one 1 g dose twice a day for 7 days with other antibiotics and medicines to treat stomach ulcers.
- **To prevent heart 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.
- The maximum recommended dose is 6 g per day.

### **Kidney problems**

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

### **If you take more Amoxicillin hard capsules than you should**

If you have taken too much Amoxicillin hard 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 urinating talk to your doctor as soon as possible. Take the medicine to show the doctor.

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

- If you forget to take a dose, take it as soon as you remember.
- Do not take the next dose too soon, wait about 4 hours before taking the next dose.
- Do not take a double dose to make up for a forgotten dose.

### **How long should you take Amoxicillin hard capsules for?**

- Keep taking Amoxicillin hard capsules for as long as your doctor has told you to, 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.
- Once you finish treatment, if you still feel unwell you should go back to see the doctor.

Thrush (a yeast infection of moist areas of the body which can cause soreness, itching and white discharge) may develop if Amoxicillin hard capsules is used for a long time. If this occurs tell your doctor.

If you take Amoxicillin hard capsules for a long time, your doctor may perform additional tests to check your kidneys, liver and blood are working normally.

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

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects although not everybody gets them.

### **Stop taking Amoxicillin hard 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 (may affect up to 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 taking Amoxicillin hard 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 surface of the mouth, eyes and genitals. 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
- Flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)).
- fever, chills, a sore throat or other signs of infection, or if you bruise easily. These may be signs of a problem with your blood cells
- the *Jarisch-Herxheimer reaction* which occurs during treatment with Amoxicillin hard capsules for Lyme disease and causes fever, chills, headache, muscle pain and skin rash.
- inflammation of the large bowel (colon) with diarrhoea (sometimes containing blood), pain and fever
- serious liver side effects may occur. They are mainly associated with people having treatment over a long period, males and elderly. You must tell your doctor 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 medicine or for up to several weeks after.

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

**Sometimes you may get less severe skin reactions such as:**

- a mildly itchy rash (round, pink-red patches), 'hive-like' swollen areas on forearms, legs, palms, hands or feet. This is uncommon (may affect up to 1 in 100 people).

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

The other possible side effects are:

**Common** (may affect up to 1 in 10 people):

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

**Uncommon** (may affect up to 1 in 100 people):

- being sick (vomiting).

**Very rare** (may affect up to 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 chance of these symptoms
- 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 type of anaemia. Signs include: tiredness, headaches, shortness of breath, dizziness, looking pale and yellowing of the skin and the whites of the eyes

- low number of white blood cells
- low number of cells involved with blood clotting
- the blood may take longer to clot than it normally would. You may notice this if you have a nosebleed or cut yourself.

**Not known** (frequency cannot be estimated from available data)

- Inflammation of the protective membrane surrounding the brain (aseptic meningitis)
- Jarisch-Herxheimer reaction (possible flu-like symptoms, headache, joint and muscle pain, body aches, sore throat, generally unwell, sweating, chills, nausea)
- Chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome)
- Drug-induced enterocolitis syndrome (DIES): DIES has been reported mainly in children receiving amoxicillin. It is a certain kind of allergic reaction with the leading symptom of repetitive vomiting (1-4 hours after drug intake). Further symptoms could comprise abdominal pain, lethargy, diarrhoea, and low blood pressure.
- Crystals in urine leading to acute renal injury
- Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)
- Inflammation of the membranes that surround the brain and spinal cord (aseptic meningitis)

### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse.

This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system:

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie).

By reporting side effects you can help provide more information on the safety of this medicine.

### 5. How to store Amoxicillin hard capsules

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of the month.

Do not store above 25°C.

Do not use this medicine if there are visible signs of deterioration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

### 6. Contents of the pack and other information

#### What Amoxicillin hard capsules contain

- Each hard capsule contains amoxicillin trihydrate equivalent to 250 mg or 500 mg of amoxicillin.
- The other ingredients are: magnesium stearate, maize starch, gelatin, erythrosine (E127), quinoline yellow (E104), titanium dioxide (E171) and red iron oxide (E172).

#### What Amoxicillin hard capsules looks like and contents of the pack

Amoxicillin 250 mg hard capsules have a scarlet cap and ivory body and are marked with 'AMOX 250'. Available in packs of 30, 100, 500 and 1000 capsules.

Amoxicillin 500 mg hard capsules have a scarlet cap and ivory body and are marked with 'AMOX 500'. Available in pack sizes of 30, 100 and 500 capsules.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder**

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

**Manufacturer**

Athlone Laboratories Limited, Ballymurray, Co. Roscommon, Ireland

**This leaflet was last revised in January 2023.**

**General advice regarding the use of antibiotics**

Antibiotics are used to treat infections caused by bacteria. They have no effect against infections caused by viruses.

Sometimes an infection caused by bacteria does not respond to a course of an antibiotic. One of the commonest reasons for this to occur is because the bacteria causing the infection are resistant to the antibiotic that is being taken. This means that they can survive and even multiply despite the antibiotic.

Bacteria can become resistant to antibiotics for many reasons. Using antibiotics carefully can help to reduce the chance of bacteria becoming resistant to them.

When your doctor prescribes a course of an antibiotic it is intended to treat only your current illness. Paying attention to the following advice will help prevent emergence of resistant bacteria that could stop the antibiotic working.

It is very important that you take the antibiotic at the right dose, at the right times and for the right number of days. Read the instructions on the label and if you do not understand anything ask your doctor or pharmacist to explain.

You should not take an antibiotic unless it has been prescribed specifically for you and you should only use it to treat the infection for which it was prescribed.

You should not take antibiotics that have been prescribed for other people even if they had an infection that was similar to yours.

You should not give antibiotics that were prescribed for you to other people.

If you have any antibiotic left over when you have taken the course as directed by your doctor you should take the remainder to a pharmacy for appropriate disposal.