

## Package leaflet – Information for the user

### Amoxicillin 125mg/5ml Powder for Oral Suspension Amoxicillin 250mg/5ml Powder for Oral Suspension

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 Oral Suspension is and what it is used for
2. What you need to know before you take Amoxicillin Oral Suspension
3. How to take Amoxicillin Oral Suspension
4. Possible side effects
5. How to store Amoxicillin Oral Suspension
6. Contents of the pack and other information

#### **1. What Amoxicillin oral suspension is and what it is used for**

##### **What Amoxicillin oral suspension is**

Amoxicillin oral suspension is an antibiotic. The active ingredient is amoxicillin trihydrate. This belongs to a group of medicines called ‘penicillins’.

##### **What Amoxicillin oral suspension is used for**

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

#### **2. What you need to know before you take Amoxicillin oral suspension**

##### **Do not take Amoxicillin oral suspension**

- if you are allergic to amoxicillin, penicillin or any of the other ingredients of 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 oral suspension if any of the above apply. If you are not sure, talk to your doctor or pharmacist before taking Amoxicillin oral suspension.

##### **Warnings and Precautions**

Talk to your doctor or pharmacist before taking Amoxicillin oral suspension 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 oral suspension.

##### **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 oral suspension. This is because Amoxicillin oral suspension can affect the results of these tests.

### **Other medicines and Amoxicillin oral suspension**

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 oral suspension 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 to stop blood clots (such as warfarin) you may need extra blood tests.
- If you are taking other antibiotics (such as tetracycline) Amoxicillin oral suspension may be less effective.
- If you are taking methotrexate (used for the treatment of cancer and severe psoriasis), Amoxicillin oral suspension 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 oral suspension 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.

### **Amoxicillin Oral Suspension 125 mg/5 ml and 250 mg/5 ml contains sucrose, sodium and sodium benzoate**

Amoxicillin 125 mg/5 ml and 250 mg/5 ml Oral Suspension contain 2.7 g of sucrose per 5 ml dose.

- This should be taken into account in patients with diabetes mellitus.
- Sucrose is absorbed as glucose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May be harmful to the teeth (during long term use e.g. for two weeks or more)

Amoxicillin 125 mg/5 ml Oral Suspension contains 3.79 mg sodium (main component of cooking/table salt) in each 5 ml. This is equivalent to 0.19% of the recommended maximum daily dietary intake of sodium for an adult.

Amoxicillin 250 mg/5 ml Oral Suspension contains 6.47 mg sodium (main component of cooking/table salt) in each 5 ml. This is equivalent to 0.32% of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 4.82 mg sodium benzoate in each 5 ml which is equivalent to 0.964 mg/ml. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

### **3. How to take Amoxicillin oral suspension**

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

- Shake bottle well before each dose
- 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.

- Your doctor will advise you how much Amoxicillin 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**

This suspension is not usually prescribed for adults and children weighing more than 40 kg. Ask your doctor or pharmacist for advice.

#### **Kidney problems**

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

#### **If you take more Amoxicillin oral suspension than you should**

If you have taken too much Amoxicillin oral suspension 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 Oral Suspension**

- 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 oral suspension for?**

- Keep taking Amoxicillin oral suspension 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 oral suspension is used for a long time. If this occurs tell your doctor.

If you take Amoxicillin oral suspension 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 oral suspension 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 having Amoxicillin Oral Suspension, 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 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 and 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 an infection, or if you bruise easily. These may be signs of a problem with your blood cells
- the *Jarisch-Herxheimer reaction* which occurs during the treatment with Amoxicillin Oral Suspension 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 the elderly. You must tell your 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 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 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
- 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 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 oral suspension**

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 and carton (after abbreviation e.g. EXP.). The expiry date refers to the last day of that month.

#### **Dry powder**

Do not store above 25°C.

Store in original container in order to protect from light.

#### **Liquid suspension**

Store in the original container

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

After reconstitution the suspension should be stored in a refrigerator between 2-8°C and used within 7 days.

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 oral suspension contains**

- The active substance is amoxicillin (as amoxicillin trihydrate).  
Amoxicillin 125 mg/5 ml oral suspension - each 5 ml of suspension contains 125 mg amoxicillin (as amoxicillin trihydrate).  
Amoxicillin 250 mg/ 5ml oral suspension - each 5 ml of suspension contains 250 mg amoxicillin (as amoxicillin trihydrate).
- The other ingredients are sodium benzoate (E211), disodium edetate, sodium citrate anhydrous, lemon flavour powder, quinoline yellow (E104) and sucrose.

### **What Amoxicillin oral suspension looks like and contents of the pack**

Your medicine comes in a bottle containing a pale yellow powder with the odour and flavour of lemon. The 125 mg/5 ml strength is available in bottles containing either 60 ml or 100 ml of suspension as prepared by the pharmacist. The 250 mg/5 ml strength is available in bottles containing 100 ml of suspension as prepared by the pharmacist. A spoon with graduations of 2.5 ml and 5 ml measures or a spoon with a 5 ml graduation may be supplied with packs of this product.

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.

1. 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.
2. 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.
3. You should not take antibiotics that have been prescribed for other people even if they had an infection that was similar to yours.
4. You should not give antibiotics that were prescribed for you to other people.
5. 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.

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**Instructions for reconstitution**

Check cap seal is intact before use.

Invert and shake bottle to loosen powder.

Fill the bottle with water to just below the mark on the bottle label.

Invert and shake well, then top up with water to the mark. Invert and shake again.

Shake well before taking each dose.