

Package leaflet: Information for the user**Amoxicillin 250mg, 500mg and 100mg Powder for Solution for Injection**

Amoxicillin Sodium (referred to as Amoxicillin in the remainder of the leaflet)

Read all of this leaflet carefully before you are given 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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Amoxicillin is and what it is used for

The name of your medicine is Amoxicillin Powder for Solution for Injection. The vials contain a medicine called amoxicillin sodium. This belongs to a group of medicines called 'penicillin'.

What Amoxicillin is used for

Amoxicillin is used to treat infections caused by bacteria in different parts of the body.

Amoxicillin Powder for Solution for Injection is usually used for urgent treatment of severe infection or if patients cannot take Amoxicillin by mouth.

2. What you need to know before you are given Amoxicillin Injection**You should not be given Amoxicillin**

- if you are allergic to amoxicillin or penicillin. There are no other ingredients in this medicine (see section 6)
- if you have had an allergic reaction to any antibiotic. This can include a skin rash or swelling of the face or throat
- if you have previously been told that your infection cannot be treated with amoxicillin or ampicillin
- Methotrexate (used to treat cancer and severe psoriasis), penicillins may reduce the excretion of methotrexate causing a potential increase in side effects
- Probenecid (used to treat gout), concomitant use of probenecid may reduce the excretion of amoxicillin and is not recommended.

You should not be given Amoxicillin if any of the above applies to you. If you are not sure speak to your doctor, nurse or pharmacist.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given Amoxicillin if you:

- have glandular fever (fever, sore throat, swollen glands and extreme tiredness)
- have kidney problems
- are not urinating regularly
- have a problem with your heart
- have undiagnosed sore throat (pharyngitis) or a type of cancer known as lymphatic lymphoma, which affects white blood cells
- have HIV.

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

Blood and urine tests

If you are having:

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

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

Children

Care should be taken in newborns and young infants as there is the chance of higher levels of amoxicillin in the blood.

Other medicines and Amoxicillin

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

- If you are taking allopurinol (used for gout) with Amoxicillin, it may be more likely that you will have an allergic skin reaction
- If you are taking probenecid (used for gout), your doctor may decide to adjust your dose of Amoxicillin
- If you are taking medicines to help stop blood clots (such as warfarin), you may need extra blood tests
- If you are taking other antibiotics (such as tetracycline) Amoxicillin may be less effective
- If you are taking methotrexate (used for the treatment of cancer and severe psoriasis) Amoxicillin 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 for advice before you are given this medicine.

Driving and using machines

Amoxicillin 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.

Important information about some of the ingredients of Amoxicillin

Amoxicillin 250mg powder for solution for injection contains 14.9mg of sodium.

Amoxicillin 500mg powder for solution for injection contains 29.7mg of sodium.

Amoxicillin 1000mg powder for solution for injection contains 59.4mg of sodium.

This should be considered if you are on a controlled sodium diet.

3. How Amoxicillin is given

You will never give yourself this medicine. A qualified person, like a doctor or a nurse, will give you this medicine.

- Your medicine will be given to you by injection into a muscle (intramuscularly) or into a vein (intravenously) or as an infusion into a vein
- Your doctor will decide how much you need each day and how often the injections should be given
- Make sure you drink plenty of fluids while having Amoxicillin.

To treat infections the usual doses are as follows:

Children up to 40kg

- **Most infections:** 20mg to 200mg for every kilogram of body weight in divided doses throughout the day
- **Lyme disease (an infection spread by parasites called ticks):** isolated erythema migrans (early stage – red or pink circular rash) 25mg to 50mg for every kilogram of body weight in divided doses throughout the day; systemic manifestations (late stage – for more serious symptoms or when the disease spreads around your body) 100mg for every kilogram of body weight in divided doses throughout the day

- **Intravenous maximum single dose:** 50mg for every kilogram of body weight

- **Intramuscular maximum daily dose:** 120mg for every kilogram of body weight as 2 to 6 equally divided doses.

Adults, elderly patients and children weighing 40kg or more

- **Usual daily dosage:** 750mg to 6g administered in divided doses
- **Intravenous maximum daily dose:** 12g per day
- **Intravenous maximum single dose:** 2g by infusion or 1g by bolus injection
- **Intramuscular maximum daily dose:** 4g per day
- **Intramuscular maximum single dose:** 1g
- **Lyme disease (an infection spread by parasites called ticks):** isolated erythema migrans (early stage – red or pink circular rash) 4g per day; systemic manifestations (late stage - for more serious symptoms or when the disease spreads around your body) 6g per day.

Patients with kidney problems

If you have kidney problems the dose might be lower than the usual dose. Amoxicillin is removed by dialysis (artificial filtration and purification of the blood). Therefore, patients receiving dialysis may require another dose of Amoxicillin at the end of their dialysis session.

If you are given more Amoxicillin than you should

This medicine is given to you by a doctor or a nurse. It is unlikely that you will be given too much, but if you think you have been given too much Amoxicillin, tell your doctor or nurse immediately. 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.

The doctor will assess your condition and decide how to treat an overdose.

If you think you have missed a dose of Amoxicillin

If you think that a dose of Amoxicillin has been missed, speak to your doctor or nurse.

How long will you need to take Amoxicillin for?

You will not normally be given Amoxicillin for more than 2 weeks without the doctor reviewing your treatment.

Thrush (a yeast infection of moist areas of the body which can cause soreness, itching and white discharge) may develop if Amoxicillin is used for a long time. If this occurs, tell your doctor, pharmacist or nurse. If you are given Amoxicillin 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 about how this product is given, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Stop taking Amoxicillin and see a doctor or nurse straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

INFORMATION FOR HEALTH CARE PROFESSIONALS**Amoxicillin 250mg Powder for Solution for Injection****Amoxicillin 500mg Powder for Solution for Injection****Amoxicillin 1g Powder for Solution for Injection**

Please refer to the Summary of Product Characteristics for further information

• Presentation

Amoxicillin Injection is available in vials containing the equivalent of 250mg, 500mg or 1g amoxicillin as amoxicillin sodium, presented as a powder for reconstitution.

• Posology and method of administration**Posology**

The dose of Amoxicillin that is selected to treat an individual infection should take into account:

- The expected pathogens and their likely susceptibility to antibacterial agents
- The severity and the site of the infection
- The age, weight and renal function of the patient

Please refer to the section 4.2 of the SmPC for further information.

The duration of therapy should be determined by the type of infection and

the response of the patient, and should generally be as short as possible. Some infections require longer periods of treatment (see section 4.4 of the SmPC regarding prolonged therapy).

Method of Administration

The standard recommended route of administration is by intravenous injection or intravenous infusion. Intramuscular administration should only be considered when the intravenous route is not possible or less appropriate for the patient.

Intravenous Injection:

Dissolve 250mg in 5mL Water for Injections Ph Eur (final volume 5.2mL). Dissolve 500mg in 10mL Water for Injections Ph Eur (final volume 10.4mL). Dissolve 1g in 20mL Water for Injections Ph Eur (final volume 20.8mL).

Amoxicillin for Injection BP, when diluted may be injected slowly into a vein or infusion line over a period of three to four minutes.

Intravenous Infusion:

Prepare as above and add to an iv solution in a minibag or in-line burette. Administer over 30 to 60 minutes. Alternatively the appropriate volume of iv fluid may be transferred from the infusion bag into the vial, using a suitable reconstitution device, and drawn back into the bag after dissolution.

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, some signs include: rashes, high temperature (fever), joint pain, 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, 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 treatment with Amoxicillin 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 which are often reversible. They are mainly associated with people having treatment over a long period, males and the elderly. You must tell your doctor or nurse 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.
- **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> <administration> <use>). 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).**

These can happen when having the medicine or for up to several weeks after.

If any of the above occurs talk to your doctor or nurse 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 or nurse 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, pharmacist or nurse
- 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
- an excessive breakdown of red blood cells causing a form 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
- inflammation of the protective membrane surrounding the brain (aseptic meningitis).

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

- Changes in your salt and electrolyte levels (shown in blood tests, e.g. low potassium)
- Hallucinations (hearing or seeing things that are not there)
- Signs of central nervous system toxicity (e.g. ringing in the ears or being sensitive to sound, difficulty in speaking, numbness of the tongue or around the mouth, fits, feeling sleepy, shakiness, blurred vision), generally associated with large intravenous doses of amoxicillin or kidney problems
- Encephalopathy (disease of the brain, e.g. confusion, fever, headache, hallucinations, paralysis, light sensitivity, disturbances in sight and movement, stiff neck), has been reported when administered into the arachnoid membrane of the brain or spinal cord and can be fatal
- Coma may develop with high doses of amoxicillin
- Difficulty breathing or shortness of breath; generally associated with large intravenous doses of amoxicillin or kidney problems
- Sore mouth and tongue.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This also includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: <http://www.mhra.gov.uk/yellowcard> or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Amoxicillin Injection

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 that month
- Store below 25°C, in the original container
- Reconstituted solutions should be used immediately after preparation.

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 protect the environment.

6. Contents of the pack and other information

What Amoxicillin contains

The active ingredient is amoxicillin sodium.

Each vial of amoxicillin 250mg powder for solution for injection contains 250mg amoxicillin as amoxicillin sodium.

Each vial of amoxicillin 500mg powder for solution for injection contains 500mg amoxicillin as amoxicillin sodium.

Each vial of amoxicillin 1000mg powder for solution for injection contains 1000mg amoxicillin as amoxicillin sodium.

There are no other ingredients. However, please see section 2 for further important information about sodium in Amoxicillin.

What Amoxicillin looks like and the contents of the pack

Amoxicillin is supplied as a vial of powder for making up as an injection.

Vials containing 250mg or 500mg of amoxicillin powder for solution for injection are available in packs of 10 vials.

Vials containing 1000mg of amoxicillin powder for solution for injection are available in single packs.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK

Manufacturer

CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK only).

Please be ready to give the following information:

Product name	Reference numbers
Amoxicillin for injection 250mg	29831/0010
Amoxicillin for injection 500mg	29831/0012
Amoxicillin for injection 1000mg	29831/0011

This is a service provided by the Royal National Institute of Blind People.

For the Republic of Ireland please call + 44 1978 661261.

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Intramuscular Injection:

Add 1.5mL Water for Injections Ph Eur to 250mg and shake vigorously (final volume 1.7mL).

Add 2.5mL Water for Injections Ph Eur to 500mg and shake vigorously (final volume 2.9mL).

The maximum single dose is 1g in adults and children \geq 40kg.

Do not inject more than 60mg/kg at one time in children < 40kg.

• Incompatibilities

If amoxicillin is prescribed concurrently with an aminoglycoside, the antibiotics should not be mixed in the syringe, intravenous fluid container or giving set because under these conditions, loss of activity of the aminoglycoside can occur. Amoxicillin and aminoglycoside injections should be administered at separate sites.

Amoxicillin should not be mixed with blood products or other proteinaceous fluids (eg protein hydrolysates) or with intravenous lipid emulsions.

Amoxicillin should not be mixed with ciprofloxacin.

Amoxicillin solutions should not be mixed with infusions containing dextran or bicarbonate.

• Shelf life and special precautions for storage

Unopened: 36 months.

Store below 25°C.

Reconstituted solutions should be administered immediately after preparation.

• Instructions for use/handling

The vials are not suitable for multidose use.

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Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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