

Amoxicillin 125 mg/5 ml Powder for Oral Suspension

Amoxicillin 250 mg/5 ml 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 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 is and what it is used for
2. What you need to know before you take Amoxicillin
3. How to take Amoxicillin
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

What Amoxicillin is

Amoxicillin is an antibiotic. The active ingredient is amoxicillin. This belongs to a group of medicines called "penicillins".

What Amoxicillin is used for

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

2 What you need to know before you take Amoxicillin

Do not take Amoxicillin:

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Amoxicillin 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.

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. This is because Amoxicillin can affect the results of these tests.

Other medicines and Amoxicillin

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, 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 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), penicillins may reduce the excretion of methotrexate causing a potential increase in side effects.

Pregnancy, breast-feeding and fertility:

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 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 contains aspartame, sodium benzoate, benzyl alcohol, benzyl benzoate, sorbitol, glucose and sulphur dioxide.

- This medicine contains 8.5 mg aspartame (E 951) in each dose. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.
- This medicine contains 7.1 mg sodium benzoate (E 211). Sodium benzoate is a mild irritant to the eyes, skin and mucous membrane. This medicine contains up to 0.44 mg benzyl benzoate in each dose. Benzyl benzoate and sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).
- This medicine contains up to 3 mg benzyl alcohol in each dose. Benzyl alcohol may cause allergic reactions. Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called "gaspings syndrome") in young children. Do not give to your newborn baby (up to 4 weeks old), unless recommended by your doctor. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist.

Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

- This medicine contains less than 1mmol (23 mg) sodium per dose, that is to say essentially sodium free.
- This medicine contains 0.14 mg sorbitol in each dose.
- This medicine contains 0.1 micrograms sulphur dioxide. May rarely cause severe hypersensitivity reactions and bronchospasm.
- This medicine contains 0.68 mg 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.

3 How to take Amoxicillin

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 usual dose is

Children weighing less than 40 kg

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

- Your doctor will advise you how much Amoxicillin you should give to your baby or child.
- The usual dose is 40 mg to 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 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 than you should:

If you have taken too much Amoxicillin, 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:

- 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 for?

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

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

The reconstitution of the suspension is carried out by the doctor or pharmacist.

To reconstitute the suspension fill the bottle with fresh tap water approx. 1 cm below the filling mark, close and shake well at once.

125 mg/5 ml powder for oral suspension:

After the foam has settled, slowly add fresh tap water exactly to the filling mark (56 ml water for 60 ml, 94 ml water for 100 ml suspension).

250 mg/5 ml powder for oral suspension:

After the foam has settled, slowly add fresh tap

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Instructions for reconstitution

The reconstitution of the suspension is carried out by the doctor or pharmacist.

After opening of the screw cap, ensure that the bottle cap seal is intact and tightly attached to the bottle rim. Do not use if not intact. Shake bottle to loosen powder. To reconstitute the suspension fill the bottle with fresh tap water approx. 1 cm below the filling mark, close and shake well at once.

125 mg/5 ml powder for oral suspension:

After the foam has settled, slowly add fresh tap water exactly to the filling mark (56 ml water for 60 ml, 94 ml water for 100 ml suspension).

250 mg/5 ml powder for oral suspension:

After the foam has settled, slowly add fresh tap water exactly to the filling mark (55 ml water for 60 ml, 92 ml water for 100 ml suspension).

Shake vigorously again.

The white to slightly yellowish suspension with fruity odour is now ready for use.

Do not use the reconstituted suspension if the colour is not white to slightly yellowish

Shake the bottle well before taking each dose.

water exactly to the filling mark (55 ml water for 60 ml, 92 ml water for 100 ml suspension).

Shake vigorously again.

The white to slightly yellowish suspension with fruity odour is now ready for use.

Shake the bottle well before taking each dose. 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** 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, 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, 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. 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
- 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 white blood cells
- low number of white blood cells
- the blood may take longer to clot than it normally would. You may notice this if you have a nosebleed or cut yourself.

Frequency not known (frequency cannot be estimated from the available data):

- 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 administration). 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 or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in 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

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 carton and bottle after EXP. The expiry date refers to the last day of that month. Do not store above 25°C. Keep the bottle tightly closed in order to protect from moisture.

In use storage conditions after reconstitution:

Store in a refrigerator (2°C - 8°C).

In use shelf life after reconstitution: 14 days

Do not use this medicine if lumps of powder are visible in the bottle before reconstitution.

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 substance is amoxicillin (as trihydrate). 5 ml reconstituted suspension contains:

Amoxicillin trihydrate corresponding to 125 mg of amoxicillin.

Amoxicillin trihydrate corresponding to 250 mg of amoxicillin.

The other ingredients are: citric acid anhydrous (E 330); sodium benzoate (E 211); aspartame (E 951); talc (E 553b); anhydrous trisodium citrate (E 331); guar (E 412); precipitated silicon dioxide (E 551); powdered lemon flavouring (containing among others: sorbitol, sulphur dioxide, glucose); powdered peach-apricot flavouring (containing among others: sorbitol, sulphur dioxide, benzyl benzoate); powdered orange flavouring (containing among others: benzyl alcohol).

What Amoxicillin looks like and contents of the pack

White to slightly yellowish powder with characteristic fruity odour.

125 mg/5 ml powder for oral suspension:

Amber glass bottles containing 5.10 g powder for 60 ml oral suspension respectively containing 8.50 g powder for 100 ml oral suspension with polypropylene screw closure (press + turn) and sealing membrane.

250 mg/5 ml powder for oral suspension:

Amber glass bottles containing 6.6 g powder for 60 ml oral suspension respectively containing 11 g powder for 100 ml oral suspension with polypropylene screw closure (press + turn) and sealing membrane.

The packaged measuring spoon with filling marks at 1.25 ml, 2.5 ml and 5.0 ml is made of polypropylene.

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| Individual packs of | 60 ml and 100 ml bottles in carton box |
| Hospital packs of | 10 x 60 ml, 20 x 60 ml, 40 x 60 ml, 10 x 100 ml and 40 x 100 ml bottles in carton box |

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Sandoz Limited, Park View, Riverside Way, Watchmoor Park, Camberley, Surrey, GU15 3YL United Kingdom

Manufacturer:

Sandoz GmbH, Biochemiestrasse 10, 6250 Kundl, Austria.

This leaflet was last revised in 02/2023.

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 the 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 use it only 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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