PACKAGE LEAFLET: INFORMATION FOR THE USER

Amoxicillin 1g dispersible tablets

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, pharmacist or nurse.
- 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, 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 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. It 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 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, pharmacist or nurse 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.

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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 to treat gout), concomitant use of probenecid may reduce the excretion of amoxicillin and is not recommended. 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 to treat cancer and severe psoriasis) penicillins may reduce the excretion of methotrexate causing a potential increase in side effects.
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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.

Amoxicilin contains 20 mg aspartame in each Amoxicillin 1000 mg tablet

Aspartame (E951) 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.

Amoxicillin contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

This medicinal product contains maltodextrin, a source of 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.

The tablets can be used in two ways. First disperse in water, then drink, or take directly with water. The tablets may be broken to ease the swallowing.

- Space the doses evenly during the day, at least 4 hours apart.

The usual dose is:

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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 dose is 100 mg for each kilogram of body weight a day.

Adults 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 of 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 causes 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.
If you have any further questions on the use of this medicine, 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 straight away, if you notice any of the following serious side effects – you may need urgent medical treatment:

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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
- 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.

The following adverse effects are of unknown frequency (cannot be estimated from the available data):

- the *Jarisch-Herxheimer reaction* which occurs during treatment with Amoxicillin for Lyme disease and causes fever, chills, headache, muscle pain and skin rash
- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (*Kounis syndrome*)
- a red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, neck [*Symmetrical Drug-Related Intertriginous and Flexural Exanthema (SDRIFE)*]
- drug-induced enterocolitis syndrome (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.

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)

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- 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 leading to acute renal injury, 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.
- inflammation of the membranes that surround the brain and spinal cord (aseptic meningitis)

Not known (Frequency cannot be estimated from the available data**)**

- rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)

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 national reporting system(see below).. By reporting side effects, you can help provide more information on the safety of this medicine.
United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard).

5. How to store Amoxicillin

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

Do not store above 25 ºC. Store in the original package in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the carton and blister after the letters "EXP". The expiry date refers to the last day of that month.

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.

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6. Contents of the pack and other information

What Amoxicillin contains
The active substance is amoxicillin.

Each dispersible tablet contains amoxicillin trihydrate equivalent to 1000 mg amoxicillin.

The other ingredients are magnesium stearate, cellulose microcrystalline, crospovidone, strawberry flavour and aspartame (E951).

Components of the strawberry flavour: maize maltodextrin, triethyl citrate, flavouring components, propylene glycol and benzyl alcohol.

What Amoxicillin looks like and contents of the pack

Amoxicillin 1g dispersible tablets
The tablets are white or o_/white 22 mm by 10 mm oblong shaped tablets with one score-line on both sides.

The tablets are packed in blisters of PVC/PVDC/Aluminium or PVC/TE/PVDC/Aluminium.

Amoxicillin 1g dispersible tablets is available in packages of 3, 6, 8, 10, 12, 14, 16, 20, 24, 30, 100 and 1000 Tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder

Special Concept Development (UK) Limited,
Units 1-7, Colonial Way,
Watford, Hertfordshire,
WD24 4YR, UK

Manufacturer
PenCef Pharma GmbH
Breitenbachstrasse 13-14
13509 Berlin, Germany

Or

Manufacturer
HAUPT Pharma Latina S.r.L.
Strada Statale 156 Monti Lepini Km. 47,600
04100 Borgo S. Michele (Latina), Italy

This medicinal product is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Netherlands - Amoxicilline Centrient 1000 mg dispergeerbare tabletten
United Kingdom (Northern Ireland) – Amoxicillin 1000 mg dispersible tablets
Spain - Amoxicilina Almus 1000 mg comprimidos dispersables
France – Amoxicilline Almus 1 g, comprimé dispersible

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This leaflet was last revised in 07/2026
Other sources of information

Detailed information on this medicine is available on the website of the MA/Agency.

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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