

PACKAGE LEAFLET

Package leaflet: Information for the patient

Amoxicillin 250 mg film-coated tablets

Amoxicillin 500 mg film-coated tablets

Amoxicillin 750 mg film-coated tablets

Amoxicillin 1000 mg film-coated 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 healthcare professional.
- 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 healthcare professional. 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 healthcare professional before taking amoxicillin.

Warnings and Precautions

Talk to your healthcare professional before taking Amoxicillin if you:

- have infectious mononucleosis (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 healthcare professional 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 healthcare professional that you are taking Amoxicillin. This is because Amoxicillin can affect the results of these tests.

Other medicines and Amoxicillin

Tell your healthcare professional, 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 healthcare professional 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.

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 healthcare professional 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.

3. How to take Amoxicillin

Always take this medicine exactly as your healthcare professional has told you. Check with your healthcare professional, if you are not sure.

You can take Amoxicillin either before, during or after meals.

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 healthcare professional 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 healthcare professional 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.

Method of administration

Swallow your tablets whole with a drink of water. Do not crush or chew the tablets.

Amoxicillin 500 mg / 1000 mg film-coated tablets

The tablet can be divided into equal doses.

Amoxicillin 750 mg film-coated tablets

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

How long should you take Amoxicillin for?

- Keep taking Amoxicillin for as long as your healthcare professional 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 healthcare professional.

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 healthcare professional.

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

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 healthcare professional as soon as possible. Take the medicine to show the healthcare professional.

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.

If you have any further questions on the use of this medicine, ask your healthcare professional.

4. Possible side effects

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

Stop taking Amoxicillin and see a healthcare professional 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
- 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 healthcare professional urgently if you get:
 - o severe diarrhoea with bleeding
 - o blisters, redness or bruising of the skin
 - o darker urine or paler stools
 - o 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 side effects occur with undetermined frequency (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 the buttocks, upper inner thighs, armpits, neck (Symmetric Drug-Related Intertriginous and Flexural Exanthema (SDRIFE)).
- 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

If any of the above happens stop taking the medicine and see your healthcare professional 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 healthcare professional 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 healthcare professional
- kidney problems
- fits (convulsions), seen in patients on high doses or with kidney problems
- dizziness
- hyperactivity
- Teeth may appear stained, this is usually reversible with brushing (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 (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)
- Inflammation of the membranes that surround the brain and spinal cord (aseptic meningitis)
- Crystals in 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

Reporting of side effects

If you get any side effects, talk to your healthcare professional. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at Website: 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

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 blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 film-coated tablets contains

The active substance is amoxicillin

Each Amoxicillin 250mg film-coated tablet contains 250mg amoxicillin as amoxicillin trihydrate.

Each Amoxicillin 500mg film-coated tablet contains 500mg amoxicillin as amoxicillin trihydrate.

Each Amoxicillin 750mg film-coated tablet contains 750mg amoxicillin as amoxicillin trihydrate.

Each Amoxicillin 1000mg film-coated tablet contains 1000mg amoxicillin as amoxicillin trihydrate.

The other ingredients are:

Tablet Core: Microcrystalline cellulose, crospovidone, magnesium stearate

Tablet coat:

Opadry QX 321A180025 containing

Macrogol poly (vinyl alcohol) grafted copolymer, talc, titanium dioxide (E171), glycerol
monocaprylocaprate type 1, poly vinyl alcohol-part hydrolysed

What Amoxicillin looks like and contents of the pack

For 250mg: White to off white, capsule shaped, film coated tablets debossed with “C” and “18” on one side and plain on other side. Approximately 13.50 mm in length and 6.00 mm in width.

For 500mg: White to off white, capsule shaped, film coated tablets, debossed with “C” and “19” separated with break line on one side and break line on other side. Approximately 16.50 mm in length and 8.00 mm in width.

For 750mg: White to off white, capsule shaped, film coated tablets debossed with “C” and “20” on one side and break line on the other side. Approximately 19.20 mm in length and 8.90 mm in width.

For 1000mg: White to off white, capsule shaped, film coated tablets, debossed with “C” and “21” separated with break line on one side and break line on other side. Approximately 21.00 mm in length and 10 mm in width.

Amoxicillin 500 mg / 1000 mg film-coated tablets

The tablet can be divided into equal doses.

Amoxicillin 750 mg film-coated tablets

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Pack sizes: PVC-PVDC / Alu blister packs consisting of: 4, 5, 6, 7, 8, 10, 12, 14, 15, 16, 20, 21, 25, 30, 35, 40, 50, 100 & 500 tablets.

Not all pack sizes may be marketed

Marketing Authorization Holder and Manufacturer

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