

Package leaflet: Information for the user

**Amoxil Vials for Injection
500 mg and 1 g
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.
- 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 Amoxil is and what it is used for
2. What you need to know before you take Amoxil
3. How to take Amoxil
4. Possible side effects
5. How to store Amoxil
6. Contents of the pack and other information

1 What Amoxil is and what it is used for

What Amoxil is

Amoxil is an antibiotic. The active ingredient is amoxicillin. This belongs to a group of medicines called ‘penicillin’.

What Amoxil is used for

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

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

2 What you need to know before you take Amoxil

Do not take Amoxil:

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

Warnings and Precautions

Talk to your doctor, pharmacist or nurse before taking Amoxil 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, pharmacist or nurse before taking Amoxil.

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, pharmacist or nurse that you are taking Amoxil. This is because Amoxil can affect the results of these tests.

Other medicines and Amoxil

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

- If you are taking allopurinol (used for gout) with Amoxil, 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 Amoxil.
- 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) Amoxil may be less effective.
- If you are taking methotrexate (used for the treatment of cancer and severe psoriasis) Amoxil 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, pharmacist or nurse for advice before taking this medicine.

Driving and using machines

Amoxil 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.

Amoxil Powder for Solution for Injection or Infusion 500 mg contains sodium

- Amoxil contains 32 mg (1.37 mmol) of sodium (the main component of cooking/table salt) per vial, which is equivalent to 1.6% of the recommended maximum daily dietary intake of sodium for an adult. This should be considered if you are on a sodium controlled diet.

Amoxil Powder for Solution for Injection or Infusion 1 g contains sodium

- Amoxil contains 63 mg (2.74 mmol) of sodium (the main component of cooking/table salt) per vial, which is equivalent to 3.2% of the recommended maximum daily dietary intake of sodium for an adult. This should be considered if you are on a sodium controlled diet.

3 How Amoxil is given

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

- Amoxil will be given as an injection or an infusion into a vein (intravenously) or muscle (intramuscularly).
- 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 Amoxil.

To treat infections

The usual doses are as follows.

Children up to 40 kg

- **Most infections:** 20 mg to 200 mg 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) 25 mg to 50 mg 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) 50 mg for every kilogram of body weight in divided doses throughout the day.
- **Intravenous maximum single dose:** 50 mg for every kilogram of body weight.
- **Intramuscular maximum daily dose:** 120 mg for every kilogram of body weight as 2 to 6 equally divided doses.

Adults, elderly patients and children weighing 40 kg or more

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

Kidney problems

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

If more Amoxil is given to you than recommended

It is unlikely you will be given too much, but if you think you have been given too much Amoxil, tell your doctor, pharmacist 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.

If you think you have missed an injection of Amoxil

Speak to your doctor, pharmacist or nurse.

How long will you need to take Amoxil for?

You will not normally be given Amoxil 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 Amoxil is used for a long time. If this occurs, tell your doctor, pharmacist or nurse.

If you are given Amoxil 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 Amoxil 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 Amoxil, 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 Amoxil 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 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 Amoxil 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 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 protective membrane surrounding the brain (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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or by searching 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 Amoxil

Amoxil Powder for Solution for Injection or Infusion is for use in hospital only. The expiry date and storage instructions stated on the label are for the doctor, pharmacist or nurse's information. The doctor, pharmacist or nurse will make up your medicine.

6 Contents of the pack and other information

What Amoxil contains

- The active substance in each vial is 500 mg or 1 g amoxicillin.
- There are no other ingredients. However, for information about sodium in Amoxil, please see section 2.
- The doctor, nurse or pharmacist will make up the injection before use using an appropriate fluid (such as Water for Injections or an injection/infusion fluid).

What Amoxil looks like and contents of the pack

Amoxil 500 mg powder for solution for injection or infusion is a white to off-white sterile powder filled into a clear glass 25 ml vial, with a chlorobutyl rubber stopper closure and a tamper evident sealing ring. Available in packs of 1 or 10 vials.

Amoxil 1 g powder for solution for injection or infusion is a white to off-white sterile powder filled into a clear glass 25 ml vial, with a chlorobutyl rubber stopper closure and a tamper evident sealing ring. Available in packs of 1, 10 or 30 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Beecham Group plc, 980 Great West Road, Brentford, Middlesex, TW8 9GS

Manufacturer:

GlaxoSmithKline Trading Services Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland
(500 mg vials only)

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 **Amoxil Vials for Injection 500 mg**
 Amoxil Vials for Injection 1 g

Reference number 00038/0222

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

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[GSK Logo]

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.

[GSK Logo]

The following information is intended for healthcare professionals only:

Amoxil Vials for Injection

500 mg and 1 g

amoxicillin

Please refer to the Summary of Product Characteristics for further information

Intravenous administration

Vial	Diluent (ml)
500 mg	10
1 g	20

Water for injections is the normal diluent.

A transient pink colouration may or may not develop during reconstitution. Reconstituted solutions are normally colourless or a pale straw colour. All solutions should be shaken vigorously before injection.

If amoxicillin 500 mg or 1 g is to be administered by direct injection, it should be administered within 20 minutes of reconstitution.

500 mg powder for solution for injection or infusion

Preparation of intravenous infusions and stability: add without delay the reconstituted solution of 500 mg (as prepared above) to 50 ml of infusion fluid.

1 g powder for solution for injection or infusion

Preparation of intravenous infusions and stability: add without delay the reconstituted solution of 1 g (as prepared above) to 100 ml infusion fluid (e.g. using a mini bag or in-line burette).

Intravenous amoxicillin may be given in a range of different intravenous fluids. Satisfactory antibiotic concentrations are retained at 20 °C in the recommended volumes of the following infusion fluids:

Intravenous solution	Stability period at 20 °C
Water for Injection Ph. Eur.	6 h
Sodium Chloride BP 0.9% w/v	4 h
Compound Sodium Chloride BPC 1959 (Ringer's solution)	2 h
Compound Sodium Lactate BP (Ringer-Lactate: Hartmann's solution)	30 min
5% Dextrose Injection BP	20 min
0.18% w/v Sodium Chloride plus 4% Dextrose BP	30 min

If reconstituted and maintained at room temperature, infusions should be completed within the times stated.

Intramuscular administration

Vial	Diluent
500 mg	2.5 ml water for injections
1 g	2.5 ml Lidocaine hydrochloride solution

The maximum single dose is 1 g.

All solutions should be shaken vigorously before injection and administered immediately after reconstitution.

Any residual antibiotic solution should be discarded.

For single use only.

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