

[DELBERT Logo]

Package leaflet: Information for the user

**Amoxicillin Delbert 500 mg
Powder for solution for injection or infusion
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 Amoxicillin Delbert 500 mg is and what it is used for
2. What you need to know before you use Amoxicillin Delbert 500 mg
3. How to take Amoxicillin Delbert 500 mg
4. Possible side effects
5. How to store Amoxicillin Delbert 500 mg
6. Contents of the pack and other information

1 What Amoxicillin Delbert 500 mg is and what it is used for

What Amoxicillin Delbert 500 mg is

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

What Amoxicillin Delbert 500 mg is used for

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

Amoxicillin 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 take Amoxicillin Delbert 500 mg

Do not take Amoxicillin Delbert 500 mg :

- 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 use Amoxicillin Delbert 500 mg if any of the above apply. If you are not sure, talk to your doctor, pharmacist or nurse before using Amoxicillin Delbert 500 mg .

Warnings and Precautions

Talk to your doctor, pharmacist or nurse before taking Amoxicillin Delbert 500 mg 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 Amoxicillin Delbert 500 mg .

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 Amoxicillin Delbert 500 mg . This is because Amoxicillin Delbert 500 mg can affect the results of these tests.

Other medicines and Amoxicillin Delbert 500 mg

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

- If you are taking allopurinol with Amoxicillin Delbert 500 mg , 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 Delbert 500 mg.
- 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 Delbert 500 mg 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 doctor, pharmacist or nurse for advice before taking this medicine.

Driving and using machines

Amoxicillin Delbert 500 mg 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 Delbert 500 mg Powder for Solution for Injection or Infusion 500 mg contains sodium

- Amoxicillin Delbert 500 mg 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.

3 How Amoxicillin Delbert 500 mg is given

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

- Amoxicillin Delbert 500 mg 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 Amoxicillin Delbert 500 mg .

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 Amoxicillin Delbert 500 mg 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 Amoxicillin Delbert 500 mg , 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 Amoxicillin Delbert 500 mg

Speak to your doctor, pharmacist or nurse.

How long will you need to use Amoxicillin Delbert 500 mg for?

You will not normally be given Amoxicillin Delbert 500 mg 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 Delbert 500 mg is used for a long time. If this occurs, tell your doctor, pharmacist or nurse.

If you are given Amoxicillin Delbert 500 mg 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 using Amoxicillin Delbert 500 mg 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 Delbert 500 mg , 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 Delbert 500 mg 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 Amoxicillin Delbert 500 mg 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.

Unknown (i.e. 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website:

www.hpra.ie.

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

5 How to store Amoxicillin Delbert 500 mg

Amoxicillin Delbert 500 mg 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 Amoxicillin Delbert 500 mg contains

- The active substance in each vial is 500 mg amoxicillin.
- There are no other ingredients. However, for information about sodium in Amoxicillin Delbert 500 mg , 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 Amoxicillin Delbert 500 mg looks like and contents of the pack

Amoxicillin Delbert 500 mg powder for solution for injection or infusion is a white to off-white sterile powder filled into a clear glass 20 ml vial, with a chlorobutyl rubber stopper closure and a tamper evident sealing ring. Available in packs of 1 or 10 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Laboratoires DELBERT

49 rue Rouelle

75015 Paris

FRANCE

Manufacturer:

MEDOCHEMIE Ltd (Factory B)

48 Iapetou street,

Agios Athanassios Industrial

Area 4101 Agios Athanassios

Limassol

CYPRUS

Or

LABORATORIO REIG JOFRÉ, S.A.,

C/ Jarama 111 Polígono Industrial,

Toledo, 45007

Toledo

Spain

This medicinal product is authorised in the Member States of the EEA under the following names:

France – Xyllomac

Ireland – Amoxicillin Delbert 500 mg

This leaflet was last revised in May2023.

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.

The following information is intended for healthcare professionals only:

**Amoxicillin Delbert 500 mg
Powder for solution for injection or infusion
amoxicillin**

Please refer to the Summary of Product Characteristics for further information

Intravenous administration

Vial	Diluent (ml)
500 mg	10

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 is to be administered by direct injection, it should be administered within 20 minutes of reconstitution.

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

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

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.

This leaflet was last revised in May 2023.