**Amoxicillin, powder for solution for injection or infusion, 125, 250, 500 mg, and 1 g**

**What is Amoxicillin?**Amoxicillin is an antibiotic. The active ingredient is amoxicillin, which belongs to a group of medicines called "penicillins."

**What is Amoxicillin used for?**Amoxicillin is used to treat infections caused by bacteria in various parts of the body.

Amoxicillin powder for solution for injection or infusion is usually used for urgent treatment of severe infections or when patients cannot take amoxicillin orally.

**When should you not use this medicine or take extra precautions?**

**When should you not use this medicine?**

• If you are allergic to amoxicillin, penicillin, or any of the ingredients in this medicine.
• If you have ever had an allergic reaction to another antibiotic, such as a rash or swelling of the face or throat.

Do not use Amoxicillin if any of the above applies to you. If you are unsure, seek advice from your doctor or pharmacist before using Amoxicillin.

**When should you take extra precautions with this medicine?**

Talk to your doctor or pharmacist before using this medicine if you:

* If you have glandular fever (fever, sore throat, swollen glands, and extreme fatigue)
* If you have kidney problems
* If you have infrequent urination
* If you are unsure whether any of the above applies to you, please speak to your doctor, pharmacist, or nurse before using Amoxicillin.
* Blood and urine tests
* Your urine needs to be examined (glucose) or if you need a blood test to assess your liver function
* An estriol test is being performed (during pregnancy to check if the baby is developing normally)

Inform your doctor or pharmacist that you are using Amoxicillin, as it may affect the results of those tests.

**Are you taking any other medicines?**In addition to Amoxicillin powder for solution for injection or infusion, are you taking any other medicines, have you recently taken any, or are you likely to take any other medicines in the near future? Please inform your doctor, pharmacist, or nurse.

* If you are taking allopurinol (used for the treatment of gout) together with Amoxicillin, the chance of an allergic skin reaction increases.
* If you are taking probenecid (used for the treatment of gout), concurrent use of probenecid can reduce the excretion of amoxicillin and is not recommended.
* If you are taking medicines to prevent blood clot formation (such as warfarin), additional blood tests may be necessary.
* If you are taking other antibiotics (such as tetracycline), Amoxicillin may not work as effectively.
* If you are taking methotrexate (used for the treatment of cancer and severe psoriasis), penicillins can reduce the excretion of methotrexate, potentially increasing the risk of side effects.

**Pregnancy and breastfeeding**Are you pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding? Please consult your doctor, pharmacist, or nurse before using this medicine.

**Driving and using machinery**Amoxicillin can cause side effects, and the symptoms (such as allergic reactions, dizziness, and convulsions) may impair your ability to drive. Do not drive or operate machinery unless you feel well. Amoxicillin powder for solution for injection or infusion contains sodium.This medicine contains 63 mg of sodium (an important component of table salt) per 1 gram of anhydrous amoxicillin. This corresponds to 3% of the recommended maximum daily intake of sodium in an adult's diet.

**How to use this medicine?**You should never administer this medicine yourself. A qualified person such as a doctor or nurse will administer this medicine to you.

* Amoxicillin will be given as an injection or infusion into a vein (intravenous) or muscle (intramuscular).
* Your doctor will determine how much you need each day and how often the injections should be given.
* Make sure to drink plenty of fluids while taking Amoxicillin.
* For treating infections, the recommended dosages are as follows:

**Children weighing up to 40 kg:**

* Most infections: 20 mg to 200 mg per kg of body weight divided throughout the day.
* Lyme disease (a disease spread by parasites called ticks): isolated erythema migrans (early stage - red or pink circular rash) 25 mg to 50 mg per kg of body weight divided throughout the day; systemic symptoms (late stage - for more severe symptoms or when the disease spreads throughout your body) 100 mg per kg of body weight divided throughout the day.
* Maximum dose per time: 50 mg per kg of body weight.
* Maximum daily dose with intramuscular administration: 120 mg per kg of body weight divided into 2 to 6 equal doses.
* Adults, elderly patients, and children weighing 40 kg or more:
* Recommended daily dose: 750 mg to 6 g divided throughout the day.
* Maximum daily dose with intravenous administration: 12 g per day.
* Maximum dose per time with intravenous administration: 2 g via infusion or 1 g via bolus injection.
* Maximum daily dose with intramuscular administration: 4 g per day.
* Maximum dose per time with intramuscular administration: 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 symptoms (late stage - for more severe symptoms or when the disease spreads throughout your body) 6 g per day.

**Kidney problems:** If you have kidney problems, the dosage may be lower than the usual dosage.

**What to do if you have received too much of this medicine**: It is unlikely that you will receive too much, but if you believe you have been given too much Amoxicillin, you should immediately notify your doctor, pharmacist, or nurse. Possible signs include stomach discomfort (nausea, vomiting, or diarrhea) or crystals in the urine, which may manifest as cloudy urine or urinary problems.

**If you think you have missed an injection of Amoxicillin:** Talk to your doctor, pharmacist, or nurse.

**How long should you use Amoxicillin?**Normally, you will not receive Amoxicillin for more than 2 weeks without your doctor reevaluating your treatment.

* Thrush (a fungal infection in moist areas of the body that can cause pain, itching, and white discharge) may occur with long-term use of Amoxicillin. If this happens, you should inform your doctor, pharmacist, or nurse.
* If you are using Amoxicillin for an extended period, your doctor may conduct additional tests to check if your kidneys, liver, and blood are functioning normally.
* If you have any other questions about the administration of this medicine, please contact your doctor, pharmacist, or nurse.

**Possible side effects**Like all medicines, this medicine can cause side effects, although not everyone gets them.
Discontinue the use of Amoxicillin and seek immediate medical attention if you experience any of the following serious side effects. You may require urgent medical treatment:

* The following side effects are very rare (may affect up to 1 in 10,000 people):
* Allergic reactions. Possible signs include itchy skin or rash, swelling of the face, lips, tongue, and body, or difficulty breathing. These reactions can be severe, and occasional fatalities have been reported.
* Skin rash or pinpoint flat red round spots under the skin or bruising. This is due to inflammation of the blood vessel wall caused by an allergic reaction. It may be accompanied by joint pain (arthritis) and kidney problems.
* A delayed allergic reaction may occur, usually 7 to 12 days after using Amoxicillin. Possible signs include skin rash, fever, joint pain, and enlargement of lymph nodes, especially under the arms.
* A skin reaction called erythema multiforme, which may present with the following symptoms: itchy, purplish-red patches on the skin, especially on the palms of the hands or soles of the feet, hive-like raised swellings on the skin, sensitive areas in the mouth, eyes, and genital area. You may have a fever and feel very tired.
* Other severe skin reactions may include changes in skin color, lumps under the skin, blistering, pimples, peeling, redness, pain, itching, and scaling. These may be accompanied by fever, headache, and body pain.
* Flu-like symptoms with skin rash, fever, swollen glands, and abnormal blood test results (such as an increased concentration of white blood cells (eosinophilia) and liver enzymes) (drug reaction with eosinophilia and systemic symptoms (DRESS)).
* Fever, chills, sore throat, or other signs of infection, or easy bruising. These may be signs of a problem with your red blood cells.
* Jarisch-Herxheimer reaction occurring during treatment with Amoxicillin for Lyme disease, causing fever, chills, headache, muscle pain, and rash.
* Inflammation of the colon with diarrhea (sometimes with blood), pain, and fever.
* • Severe liver side effects. These primarily occur in people treated for extended periods, males, and the elderly. You should urgently contact your doctor in case of:
* Severe diarrhea with bleeding
* Blisters, redness, or bruising of the skin
* Dark urine or paler stools
* Yellowing of the skin or whites of the eyes (jaundice). Also, see further information on anemia that could result in jaundice.
* These side effects can occur while taking the medicine or several weeks after. If you experience any of the aforementioned side effects, discontinue the medicine and seek immediate medical attention.
* Sometimes, less severe skin reactions may occur, such as:

A mildly itchy rash (red or pinkish-red spots), hive-like swollen areas on the forearms, legs, palms, hands, or feet. This side effect occurs occasionally (may affect up to 1 in 100 people).

If you experience any of these side effects, you should inform your doctor as Amoxicillin needs to be discontinued.

Other possible side effects include:

**Common (may affect up to 1 in 10 people):**

• Skin rash

• Nausea

• Diarrhea

**Uncommon (may affect up to 1 in 100 people):**

• Vomiting

**Very rare (may affect up to 1 in 10,000 people):**

• Thrush (a fungal infection of the vagina, mouth, or skin folds). Your doctor or pharmacist can provide treatment for thrush.

• Kidney problems

• Seizures (convulsions), observed in patients receiving high doses or patients with kidney problems

• Dizziness

• Hyperactivity

• The tongue may turn yellow, brown, or black and may have a furry appearance

• Excessive breakdown of red blood cells, resulting in a specific type of anemia. Possible signs include fatigue, headache, shortness of breath, dizziness, pale appearance, and yellowing of the skin and whites of the eyes.

• Low white blood cell count

• Low number of cells involved in blood clotting

• Blood may take longer than normal to clot. You may notice this if you have a nosebleed or when you cut yourself.

Unknown frequency (cannot be determined from available data):

• Chest pain associated with allergic reactions. This could be a symptom of an allergy-induced heart attack (Kounis syndrome).

• Drug-induced enterocolitis syndrome (DIES):

DIES has mainly been reported in children receiving amoxicillin. It is a specific form of allergic reaction with the main symptom being repeated vomiting (1-4 hours after administration of the medicine). Other symptoms may include abdominal pain, lethargy, low energy, excessive sleepiness, diarrhea, and low blood pressure.

• Crystals in the urine, leading to acute kidney injury.

• Rash with circular blistering and central crusting or as a string of pearls (linear IgA disease).

• Inflammation of the membranes surrounding the brain and spinal cord (aseptic meningitis).

**How to store this medicine?**

Amoxicillin powder for solution for injection is for hospital use only. The expiration date and storage instructions on the label of the cardboard box are information for the doctor, pharmacist, or nurse. Your medicine will be prepared by the doctor, pharmacist, or nurse. When administered directly into a muscle or vein, it should be used immediately after reconstitution (usually taking about 5 minutes). (If Amoxicillin is administered via a slow infusion, it will take approximately half to one hour.)