

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **Amoxicillin 250mg, 500mg or 1g, Powder for Solution for Injection or Infusion** Amoxicillin

**Read all of this leaflet carefully before you are given 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 Injection is and what it is used for
2. What you need to know before you are given Amoxicillin Injection
3. How Amoxicillin Injection is given
4. Possible side effects
5. How to store Amoxicillin Injection
6. Contents of the pack and other information

The name of your medicine is “Amoxicillin 250mg, 500mg, 1g Powder for Solution for Injection or Infusion” (referred to as **Amoxicillin Injection** throughout this leaflet).

## **1. WHAT AMOXICILLIN INJECTION IS AND WHAT IT IS USED FOR**

### **What Amoxicillin Injection is**

Amoxicillin Injection is an antibiotic. The active ingredient is amoxicillin. This belongs to a group of medicines called ‘penicillins’.

### **What Amoxicillin Injection is used for**

Amoxicillin Injection is used to treat infections caused by bacteria in different parts of the body. Amoxicillin Injection 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 ARE GIVEN AMOXICILLIN INJECTION**

### **You must not be given Amoxicillin Injection:**

- if you are allergic to amoxicillin or penicillin
- if you have ever had an allergic reaction to any antibiotic. This can include a skin rash or swelling of the face or throat.

You must not be given Amoxicillin Injection if any of the above apply.

If you are not sure, talk to your doctor, pharmacist or nurse before you are given Amoxicillin Injection.

### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before you are given Amoxicillin Injection 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 you are given Amoxicillin Injection.

### **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 being given Amoxicillin Injection. This is because Amoxicillin can affect the results of these tests.

#### **Other medicines and Amoxicillin Injection:**

Tell the 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) while being given Amoxicillin Injection, 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.
- 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 Injection 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 breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before you are given 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.

#### **Amoxicillin injection contains sodium**

250 mg vial: This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

500 mg/1 g vials: This medicine contains 38 mg sodium in each 500 mg vial and 76 mg sodium in each 1g vial (main component of cooking/table salt). This is equivalent to 1.9% or 3.8% of the recommended maximum daily dietary intake of sodium for an adult.

### **3. HOW AMOXICILLIN INJECTION IS GIVEN**

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

- Amoxicillin 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 you are being treated with Amoxicillin Injection.

The recommended 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) 100 mg for every kilogram of body weight in divided doses throughout the day.

**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**

- **Recommended daily dosage:** 750 mg to 6 g administered in divided doses.
- **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.

**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.

#### **Kidney problems**

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

#### **If more Amoxicillin Injection 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 Injection, 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**

Speak to your doctor, pharmacist or nurse.

#### **How long will you be given Amoxicillin Injection for?**

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

If you are given 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 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.

**Talk to a doctor or nurse straight away if you notice any of the following serious side effects – you may need urgent medical treatment:**

**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
- the *Jarisch-Herxheimer reaction* which occurs during treatment with Amoxicillin 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.

**Frequency not known** (frequency cannot be estimated from 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.

These serious side effects can happen when you are being given 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 will need to be stopped.**

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
- 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.

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

- crystals in urine leading to acute kidney 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, nurse, or pharmacist. 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](http://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 INJECTION**

Amoxicillin Injection 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. When administered directly into a muscle or a vein, it should be used immediately following reconstitution (usually this process takes about 5 minutes). If Amoxicillin Injection is being administered by slow infusion this takes about half to one hour.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Amoxicillin Injection contains**

The active substance in each vial is 250 mg, 500 mg or 1 g amoxicillin.

There are no other ingredients. However, for information about sodium in Amoxicillin Injection, 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 Injection looks like and contents of the pack:**

Amoxicillin Injection is a white or almost white powder filled into a glass vial.

Each carton contains 1, 5, 10, 20 or 50 glass vials.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder:**

Ibigen S.r.l.

04011 Aprilia (Lt), Via Fossignano, 2, Italy

### **Manufacturer:**

Istituto Biochimico Italiano G. Lorenzini S.p.A.

04011 Aprilia (Lt), Via Fossignano, 2, Italy

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### **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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### **INFORMATION FOR THE HEALTHCARE PROFESSIONAL**

**The following information is intended for medical or healthcare professionals only.**

#### **Intravenous administration**

<b>Vial</b>	<b>Diluent (ml)</b>	<b>Final volume (ml)</b>
250 mg	5	5.2
500 mg	10	10.4
1 g	20	20.8

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.

#### **Preparation of intravenous infusions and stability:**

**250 mg:** add without delay the reconstituted solution of 250 mg (as prepared above - these are minimum volumes) to 50 ml of infusion fluid.

**500 mg:** add without delay the reconstituted solution of 500 mg (as prepared above - these are minimum volumes) to 50 ml of infusion fluid.

**1g:** add without delay the reconstituted solution of 1 g (as prepared above - these are minimum volumes) 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:

- Water for Injection
- NaCl
- Ringer NaCl
- Sodium lactate
- Ringer sodium lactate
- Glucose
- NaCl - Glucose

Amoxicillin is less stable in infusions containing carbohydrate.

Reconstituted solutions of amoxicillin may be injected into the drip tubing over a period of 0.5 to 1 hour.

**Intramuscular administration**

<b>Vial</b>	<b>Diluent</b>
250 mg	1.5 ml water for injections (final volume: 1.7 ml)
500 mg	2.5 ml water for injections (final volume: 2.9 ml) or 5.1 ml benzyl alcohol solution (final volume: 5.5 ml)
1 g	2.5 ml lidocaine hydrochloride solution (final volume: 3.3.ml)

All solutions should be shaken vigorously before injection and administered within 30 minutes of reconstitution.

Any residual antibiotic solution should be discarded.

For single use only.