

	Customer	Rudipharm_(UK)	Colours Used
	Product Name	Amoxicillin Suspension 125mg/5ml & 250mg/5ml_100ml	Black
	Description	40 GSM, Bible Paper	
	Size	L: 155 x H: 370 mm	
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Pharmacode Reading Direction  
← 2349

PACKAGE LEAFLET: INFORMATION FOR THE USER

## AMOXICILLIN SUGAR FREE SUSPENSION 125 MG / 5 ML & 250 MG / 5 ML (amoxicillin trihydrate)

Read all of this leaflet carefully before you start taking/using 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 or pharmacist.
- 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 doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet:

1. What Amoxicillin Suspension is and what it is used for
2. What you need to know before you take Amoxicillin Suspension
3. How to take Amoxicillin Suspension
4. Possible side effects
5. How to store Amoxicillin Suspension
6. Contents of the pack and other information

### 1. WHAT AMOXICILLIN SUSPENSION IS AND WHAT IT IS USED FOR

#### What Amoxicillin suspension is

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

#### What Amoxicillin suspension is used for

Amoxicillin suspension is used to treat infections caused by bacteria in different parts of the body. Amoxicillin suspension may also be used in combination with other medicines to treat stomach ulcers.

### 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AMOXICILLIN SUSPENSION

#### Do not take Amoxicillin Suspension

- if you are allergic (hypersensitive) to amoxicillin trihydrate, penicillin (or cephalosporins or any other antibiotics) or any of the other ingredients in this medicinal product. See 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 suspension if any of the above apply. If you are not sure, talk to your doctor or pharmacist before taking Amoxicillin suspension.

#### Warnings and Precautions

Talk to your doctor or pharmacist before taking Amoxicillin suspension 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 or pharmacist before taking Amoxicillin suspension.

#### Blood and urine tests

If you are having:

- Urine tests (glucose) or blood tests for liver function
- Oestrial tests (used during pregnancy to check the baby is developing normally)

Tell your doctor or pharmacist that you are taking Amoxicillin. This is because Amoxicillin can affect the results of these tests.

#### Other medicines and Amoxicillin suspension

Tell your doctor or pharmacist 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 for gout), your doctor 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 for the treatment of cancer and severe psoriasis), penicillins may reduce the excretion of methotrexate causing a potential increase in side effects.
- Probenecid (used to treat gout), concomitant use of probenecid may reduce the excretion of amoxicillin and is not recommended.

If you are taking methotrexate (used for the treatment of cancer and severe psoriasis) Amoxicillin 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 or pharmacist 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.

#### Amoxicillin Suspension contains sodium benzoate, sorbitol and sodium

This medicinal product contains

- Sodium Benzoate (E210); This medicine contains 82 mg benzoate salt in each 100ml, which is equivalent to 4.1 mg benzoic acid per 5ml. Benzoate salt may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).
- Sorbitol (E420); this medicine contains 16 g sorbitol in each 100ml which is equivalent to 800 mg per 5ml.
- Sodium; this medicine contains less than 1 mmol sodium (23 mg) per 5ml, that is to say essentially 'sodium-free'.

### 3. HOW TO TAKE AMOXICILLIN SUSPENSION

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

#### METHOD AND ROUTE OF ADMINISTRATION

Shake the bottle well before taking each dose. Space the doses evenly during the day, at least 4 hours apart.

#### The recommended dose is:

##### Children weighing less than 40 kg

All doses are worked out depending on the child's body weight in kilograms.

The daily dosage for children is 40 - 90 mg/kg/day in two to three divided doses (not exceeding 3 g/day) depending on the indication, severity of the disease and the susceptibility of the pathogen.

The maximum recommended dose is 100 mg for each kilogram of body weight a day.

##### Adults, elderly patients and children weighing more than 40 kg

This suspension is not usually prescribed for adults and children weighing more than 40 kg. Ask your doctor or pharmacist for advice.

#### Kidney problems

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

#### If you take more Amoxicillin Suspension than you should

If you have taken too much Amoxicillin suspension, 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 doctor as soon as possible. Take the medicine to show the doctor.

#### If you forget to take Amoxicillin Suspension

- 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 stop taking Amoxicillin Suspension

- Keep taking Amoxicillin suspension for as long as your doctor 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 doctor.

Thrush (a yeast infection of moist areas of the body which can cause soreness, itching and white discharge) may develop if Amoxicillin suspension is used for a long time. If this occurs tell your doctor.

If you take Amoxicillin suspension 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 on the use of this medicine, ask your doctor or pharmacist.

### 4. POSSIBLE SIDE EFFECTS

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

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).

Stop taking Amoxicillin 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 suspension, 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 suspension 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:
  - 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.

If any of the above happens stop taking the medicine and see your doctor 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 as Amoxicillin will need to be stopped. The other possible side effects are:

#### Common (may affect up to 1 in 10 people)

- nausea (feeling of sickness)
- diarrhoea
- skin rash

#### Uncommon (may affect up to 1 in 100 people)

- 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 or pharmacist
- 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

- teeth may appear stained, usually returning to normal with brushing (this has been 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.

#### 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](http://www.mhra.gov.uk/yellowcard) or 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 AMOXICILLIN SUSPENSION

Keep out of sight and reach of children

Do not store above 25°C.

Do not use this medicine after the expiry date printed on the pack.

Keep the suspension tightly closed.

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

The reconstituted sugar free Suspension should be used within 7 days of preparation.

Return any sugar free Suspension not used by this time to the pharmacist.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### 6. CONTENT OF THE PACK AND OTHER INFORMATION

#### What Amoxicillin Suspension contains

The active ingredient in Amoxicillin Suspension 125 mg/5 ml and 250 mg/5ml is Amoxicillin Trihydrate EP equivalent to Amoxicillin EP 250 mg.

The other ingredients are Sodium Benzoate (E211), Disodium Edetate, Sodium Citrate, Citric Acid, Colloidal Anhydrous Silica, Sorbitol (E420), Saccharin Sodium, Banana Flavour, Xanthan Gum.

#### What Amoxicillin Suspension looks like and contents of the pack

Pack size - 100 ml



Marketing Authorisation Holder:  
**Rudipharm Limited**  
Unit 6, Salbrook Road Industrial Estate  
Salbrook Road, Redhill, Surrey, RH1 5GJ, UK

Manufacturer:  
**Rudipharm Limited**  
Oak House, Reeds Crescent  
Watford, WD24 4QP, UK

#### POM

This leaflet was last revised in August 2025.

To listen to or request a copy of this leaflet in Braille, large print or audio please call, 01293 827819 (UK only)

Please be ready to give the following information:

**Product name**  
Amoxicillin Sugar Free Suspension 125 mg/5 ml

**Reference number**

PL 49565/0001

**Product name**  
Amoxicillin Sugar Free Suspension 250 mg/5 ml

**Reference number**

PL 49565/0002

IP192004

370 mm

155 mm

155 mm

3341  
Pharmacode Reading Direction

PREPARED BY:	CHECKED BY PRODUCTION:	CHECKED BY RA:	CHECKED BY PDC:	APPROVED BY CUSTOMER:	CHECKED BY MILAN QA:	APPROVED BY MILAN QA:
		NA				