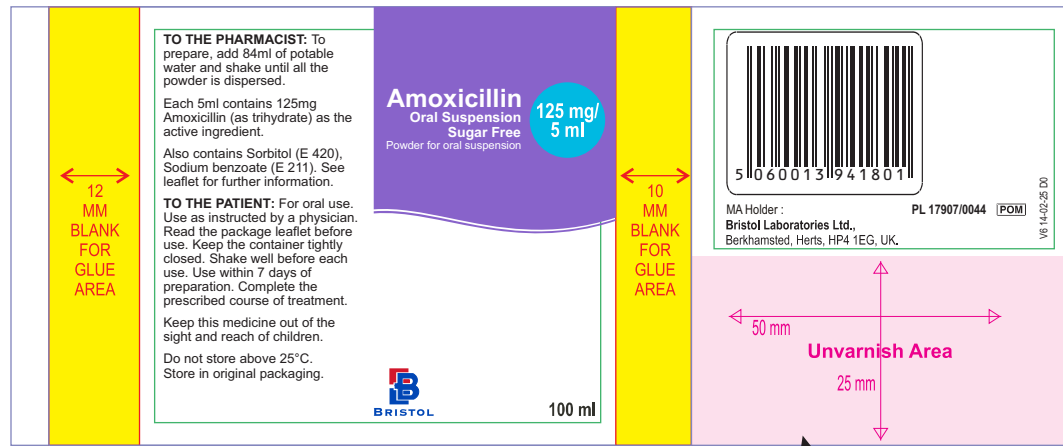


UNWINDING DIRECTION



BASE LABEL

- 306 C
- 265 C
- Black
- 186C
- 2728 C

Base Label
Size: 140 x 58 mm
Kaypee Design

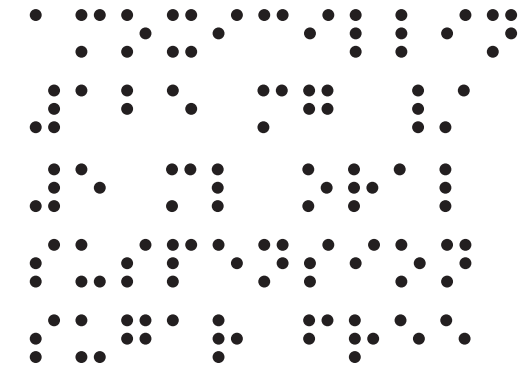


Artwork Same Size
Size: 436 x 58 mm

Kaypee Design

- 306 C
- 265 C
- Black
- 186C
- 2728 C

**Amoxicillin
#125 mg /
#5 ml Oral
Suspension
sugar free**



BN:
EXP:

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<p>TO THE PHARMACIST: To prepare, add 84ml of potable water and shake until all the powder is dispersed.</p> <p>Each 5ml contains 125mg Amoxicillin (as trihydrate) as the active ingredient.</p> <p>Also contains Sorbitol (E 420), Sodium benzoate (E 211). See leaflet for further information.</p> <p>TO THE PATIENT: For oral use. Use as instructed by a physician. Read the package leaflet before use. Keep the container tightly closed. Shake well before each use. Use within 7 days of preparation. Complete the prescribed course of treatment.</p> <p>Keep this medicine out of the sight and reach of children. Do not store above 25°C. Store in original packaging.</p> <p>Amoxicillin Oral Suspension Sugar Free 125 mg / 5 ml Powder for oral suspension</p> <p>100 ml</p> <p>Ph. Code</p>	<p>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</p> <p>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</p> <p>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)).</p> <p>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 <i>Jarisch-Herxheimer reaction</i> which occurs during treatment with Amoxicillin for Lyme disease and causes fever, chills, headache, muscle pain and skin rash.</p> <p>inflammation of the large bowel (colon) with diarrhoea (sometimes containing blood), pain and fever</p> <p>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:</p> <ul style="list-style-type: none"> o severe diarrhoea with bleeding 	<ul style="list-style-type: none"> 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. <p>These can happen when having the medicine or for up to several weeks after.</p> <p>If any of the above happens stop taking the medicine and see your doctor straight away.</p> <p>Sometimes you may get less severe skin reactions such as:</p> <ul style="list-style-type: none"> o 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). <p>If you have any of these talk to your doctor as Amoxicillin will need to be stopped.</p> <p>The other possible side effects are:</p> <p>Common (may affect up to 1 in 10 people)</p> <ul style="list-style-type: none"> o skin rash o feeling sick (nausea) o diarrhoea. <p>Uncommon (may affect up to 1 in 100 people)</p> <ul style="list-style-type: none"> o being sick (vomiting). <p>Vary rare (may affect up to 1 in 10,000 people)</p> <ul style="list-style-type: none"> o thrush (a yeast infection of the vagina, mouth or skin folds), you can get treatment for thrush from your doctor or pharmacist o kidney problems 	<ul style="list-style-type: none"> o fits (convulsions), seen in patients on high doses or with kidney problems o dizziness o hyperactivity o teeth may appear stained, usually returning to normal with brushing (this has been reported in children) o the tongue may change to yellow, brown or black and it may have a hairy appearance o 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 o low number of white blood cells o low number of cells involved with blood clotting o the blood may take longer to clot than it normally would. You may notice this if you have a nosebleed or cut yourself. <p>Frequency Not Known</p> <ul style="list-style-type: none"> o Chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome) <p>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.</p> <ul style="list-style-type: none"> o rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease) 	<ul style="list-style-type: none"> o crystals in the urine leading to acute renal injury. o inflammation of the membranes that surround the brain and spinal cord (aseptic meningitis) <p>Reporting of side effects</p> <p>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 Website: 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.</p> <p>5. How to store this medicine</p> <ul style="list-style-type: none"> o Keep this medicine out of the sight and reach of children. o Do not store above 25°C. Keep the bottle tightly closed. Store in the original packaging. o Do not use this medicine after the expiry date shown on the label after EXP. The expiry date refers to the last day of that month. o Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment. <p>6. Contents of the pack and other information</p> <p>What Amoxicillin Oral Suspension SF contains</p> <ul style="list-style-type: none"> o There are two strengths available, each 5ml of the suspension either contains 125mg or 250mg of the active ingredient Amoxicillin (as amoxicillin trihydrate). o The other ingredients are: sodium benzoate (E211), disodium edetate, sodium citrate, <p>citric acid anhydrous, sorbitol (E420), colloidal anhydrous silica, saccharin sodium, banana flavour, quinoline yellow (E104) and xanthan gum.</p> <p>Amoxicillin Oral Suspension SF is a banana flavoured suspension.</p> <p>Amoxicillin Oral Suspension is presented as a powder in bottles for preparing 100ml of suspension.</p> <p>Marketing Authorisation Holder and Manufacturer</p> <p>Name and address: Bristol Laboratories Ltd, Unit 3, Canalside, Northbridge Road, Berkhamsted, Hertfordshire, United Kingdom, HP4 1EG Telephone: 0044 (0)1442 200922 Email: info@bristol-labs.co.uk</p> <p>Amoxicillin 125mg/5ml Oral Suspension Sugar Free; PL 17907/0044</p> <p>This leaflet was last revised in February 2025.</p> <p>To request a copy of this leaflet in Braille, large print or audio format, please contact the marketing authorisation holder at the address (or telephone, email) above.</p>
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<p>Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.</p> <ul style="list-style-type: none"> o Keep this leaflet. You may need to read it again. o If you have any further queries, ask your doctor or pharmacist. <p>This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.</p> <p>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.</p> <p>What is in this leaflet:</p> <ol style="list-style-type: none"> 1. What this medicine is and what it is used for 2. What you need to know before you take this medicine 3. How to take this medicine 4. Possible side effects 5. How to store this medicine 6. Contents of the pack and other information <p>1. What this medicine is and what it is used for</p> <p>Amoxicillin is an antibiotic. The active ingredient is amoxicillin. This belongs to a group of medicines called 'penicillin'.</p> <p>Amoxicillin is used to treat infections caused by bacteria in different parts of the body. Amoxicillin may also be used in combination with other medicines to treat stomach ulcers.</p> <p>2. What you need to know before you take this medicine</p>	<p>Do not take this medicine if you:</p> <ul style="list-style-type: none"> o Are allergic to amoxicillin, PENICILLINS, cephalosporins or to any of the other ingredients of this medicine (listed in section 6). o have ever had an allergic reaction to any antibiotic. This can include a skin rash or swelling of the face or throat. <p>Do not take Amoxicillin if any of the above apply. If you are not sure, talk to your doctor or pharmacist before taking Amoxicillin.</p> <p>Warnings and precautions</p> <p>Talk to your doctor or pharmacist before taking Amoxicillin if you:</p> <ul style="list-style-type: none"> o have glandular fever (fever, sore throat, swollen glands and extreme tiredness) o have kidney problems o are not urinating regularly. <p>If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Amoxicillin.</p> <p>Conditions you need to look out for</p> <p>Amoxicillin can make some existing conditions worse, or cause serious side effects, such as severe allergic reactions, chest pain, serious skin reactions, or severe diarrhoea (pseudomembranous colitis). You must look out for certain symptoms while you are receiving Amoxicillin to help reduce the risk of any problems (see section 4).</p> <p>Blood and urine tests</p> <p>If you are having:</p> <ul style="list-style-type: none"> o Urine tests (glucose) or blood tests for liver function 	<ul style="list-style-type: none"> o Oestriol tests (used during pregnancy to check the baby is developing normally) <p>Tell your doctor or pharmacist that you are taking Amoxicillin. This is because Amoxicillin can affect the results of these tests</p> <p>Other medicines and Amoxicillin</p> <p>Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.</p> <ul style="list-style-type: none"> o If you are taking allopurinol (used for gout) with Amoxicillin, it may be more likely that you will have an allergic skin reaction. o Probenecid (used to treat gout), concomitant use of probenecid may reduce the excretion of amoxicillin and is not recommended. o If you are taking medicines to help stop blood clots (such as warfarin), you may need extra blood tests. o If you are taking other antibiotics (such as tetracycline) Amoxicillin may be less effective. o Methotrexate (used to treat cancer and severe psoriasis), penicillins may reduce the excretion of methotrexate causing a potential increase in side effects. <p>Pregnancy, breast-feeding and fertility</p> <p>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.</p> <p>Driving and using machines</p> <p>Amoxicillin can have side effects and the symptoms (such as allergic reactions, dizziness and convulsions) may make you unfit to drive.</p>	<p>Do not drive or operate machinery unless you are feeling well.</p> <p>Important information about some of the ingredients of this medicine</p> <ul style="list-style-type: none"> o This medicine contains Sorbitol. o Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. o Sodium benzoate: This medicine contains 4.82 mg sodium benzoate in each 5 ml which is equivalent to 0.964 mg per ml. o Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old). <p>Information on sodium content</p> <p>This medicine contains less than 1 mmol sodium (23 mg) per 5ml, that is to say essentially 'sodium-free'.</p> <p>3. How to take this medicine</p> <ul style="list-style-type: none"> o Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. o Shake bottle well before each dose. o Space the doses evenly during the day, at least 4 hours apart <p>The usual dose is: Children weighing less than 40 kg</p>	<ul style="list-style-type: none"> o All doses are worked out depending on the child's body weight in kilograms. o Your doctor will advise you how much Amoxicillin you should give to your baby or child. o The usual dose is 40 mg to 90 mg for each kilogram of body weight a day given in two or three divided doses. o The maximum recommended dose is 100 mg for each kilogram of body weight a day. <p>Adults, elderly patients and children weighing 40 kg or more</p> <p>This suspension is not usually prescribed for adults and children weighing more than 40 kg. Ask your doctor or pharmacist for advice.</p> <p>Kidney problems</p> <p>If you have kidney problems the dose might be lower than the usual dose.</p> <p>If you take more Amoxicillin than you should</p> <p>If you have taken too much Amoxicillin, 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.</p> <p>If you forget to take Amoxicillin</p> <ul style="list-style-type: none"> o If you forget to take a dose, take it as soon as you remember. o Do not take the next dose too soon, wait about 4 hours before taking the next dose. o Do not take a double dose to make up for a forgotten dose. <p>How long should you take Amoxicillin for?</p> <ul style="list-style-type: none"> o Keep taking Amoxicillin 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. 	<p>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 is used for a long time. If this occurs tell your doctor.</p> <p>If you take Amoxicillin for a long time, your doctor may perform additional tests to check your kidneys, liver and blood are working normally.</p> <p>If you have any further questions on the use of this medicine, ask your doctor or pharmacist.</p> <p>4. Possible Side Effects</p> <p>Like all medicines, this medicine can cause side effects, although not everybody gets them.</p> <p>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.</p> <p>The following are very rare (may affect up to 1 in 10,000 people)</p> <ul style="list-style-type: none"> o 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 o 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 o 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
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