

AMOKSICILIN ORAL SUSPENSION

250 mg/5 ml

AMOXICILLIN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 or pharmacist • 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 • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What Amoxicillin is and what it is used for
2. What you need to know before you take Amoxicillin
3. How to take Amoxicillin
4. Possible side effects
5. How to store Amoxicillin

1. WHAT AMOXICILLIN IS AND WHAT IT IS USED FOR

Amoxicillin is one of a group of antibiotic medicines called penicillins. Amoxicillin kills bacteria by interfering in the manufacture of the bacterial cell wall.

Amoxicillin can treat a wide range of bacterial infections including the following:

- chest (bronchitis or pneumonia)
- tonsils (tonsillitis)
- sinuses (sinusitis)
- heart (endocarditis)
- blood (septicaemia)
- kidneys
- ears (otitis media)
- the bladder or the urethra (the tube which carries urine from the bladder),
- infections associated with pregnancy and childbirth (puerperal sepsis and septic abortion)
- abdomen (intra-abdominal sepsis and peritonitis)
- skin, bone, teeth and gums (abscesses).

Amoxicillin can also be used to treat:

- gonorrhoea (a sexually transmitted infection)
- typhoid and paratyphoid (fevers caused by a group of bacteria called Salmonella).

Amoxicillin may also be used in combination with other medicines to treat stomach ulcers.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AMOXICILLIN

Do not take Amoxicillin if:

- You are allergic to Amoxicillin or any of the other ingredients of this medicine
- You have ever had a bad reaction or allergy to any penicillin-type antibiotic
- You ever had a skin rash or swelling of the face or neck or shortness of breath when taking any antibiotic?
- You are pregnant, planning to become pregnant or breast feeding?
- You have an intolerance to some sugars (hereditary fructose intolerance)

Prolonged use of an antibiotic may result in infections due to bacteria resistant to the antibiotic.

This medicinal product contains sucrose and sodium benzoate. Sucrose is broken down in the digestive system, by substances called enzymes, into glucose and fructose and thus is unsuitable for patients who suffer from fructose intolerance, glucose-galactose malabsorption syndrome (faulty absorption from the digestive tract) or a deficiency in the enzyme which breaks down sucrose.

Sodium benzoate may increase the risk of jaundice (yellowing of the skin or the whites of the eyes) in newborn babies.

Warnings and precautions

Talk to your doctor or pharmacist before taking Amoxicillin if:

- You suffer from kidney disease or kidney problems, as you may require a lower dose than normal
- You are not passing urine regularly
- You have glandular fever

Having urine or blood tests:

If you are having urine tests for diabetes (sugar in the urine) or blood tests for liver function let the doctor know. Amoxicillin can affect the results of these tests.

Other Medicines and Amoxicillin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, even those not prescribed by a doctor. In particular tell your doctor if you are taking any of the following:

- Anticoagulants e.g. warfarin, phenindione
- Chemotherapy drugs e.g. methotrexate
- Drugs used to treat gout (which can be caused by the build-up of uric acid) e.g. probenecid, allopurinol, sulfinpyrazone
- Some other antibiotics (e.g. neomycin and tetracyclines can reduce the effect of amoxicillin)
- Oral typhoid vaccine (may not work if taken with amoxicillin)
- Some penicillins may increase the effects of muscle relaxing drugs given as part of an anaesthetic for surgery. Tell the doctor you are taking amoxicillin if you need to have an anaesthetic.

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.

3. HOW TO TAKE AMOXICILLIN

Always take your medicine exactly as your doctor or pharmacist has told you. The pharmacist's label should tell you how much to take and how often. If it does not or you are not sure ask your doctor or pharmacist.

The maximum daily dose is 6 g given in divided doses.

Dosage:

Note: One teaspoon is equivalent to 5ml

Adults (including the elderly):

- The usual dose for most infections is 5ml of 250mg/5ml to be taken 3 times a day.
- For more serious infections the dose may be doubled to 10ml of 250mg/5ml 3 times a day.
- High doses may be given in the following conditions:
 - For severe or recurrent chest infections a dose of 3 g twice daily given orally is usually recommended
 - For simple urinary tract infections the adult dose is two 3g doses given orally with 10 to 12 hours between doses (short course)
 - For the treatment of dental abscesses two 3 g doses given orally with 8 hours between doses is recommended
 - For gonorrhoea a single 3g dose given orally is recommended

The following are the usual adult dosages for preventing infection during dental or other surgery:

- If a general anaesthetic is not used, 3g given orally one hour before surgery and another dose six hours later if necessary
- If a general anaesthetic is used, 3g given orally four hours before anaesthesia and 3g six hours after the initial dose

Children:

- Children weighing more than 40kg should be given the usual adult dosage
- Children under 40kg:
 - The usual dose for most infections is 2.5ml of 250mg/5ml 3 times a day.
 - For more serious infections the dose may be doubled to 5ml of 250mg/5ml 3 times a day.
 - In severe or frequent ear infections, a dose of 750mg (15 ml of the 250mg/5ml) may be given twice a day for two days in children aged 3 to 10 years
 - The dose for preventing infection during dental procedures or other surgery is 1.5g given orally one hour before surgery

If you take more Amoxicillin that you should

If you take more Amoxicillin that you should, tell your doctor or pharmacist immediately.

You should take this leaflet and any medicine you still have to show the doctor.

Severe cases of nausea, vomiting and diarrhoea can be treated with rehydration therapy, by drinking fluids containing sodium, water and sugar to prevent dehydration.

If you forget to take Amoxicillin

If you forget to take a dose, take it as soon as you remember, unless it is within an hour of your next dose, then carry on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Amoxicillin

Keep taking this medicine until it is finished or your doctor tells you to stop. Do not stop taking it just because you feel better. If you stop taking the medicine, some bacteria may survive and cause the infection to come back, or your condition may re-occur or get worse.

You should make sure you have several drinks of water each day unless told otherwise by your doctor. If you are still unwell after taking all the medicine, go and see your doctor. Never take more than the recommended dose each day. 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.

If you experience any of the following events STOP taking your medicine, tell your doctor or go to your nearest hospital immediately:

- Hypersensitivity or severe allergic reaction including swollen face or breathing problems
- Severe diarrhoea with bleeding
- Allergic skin reactions with itching e.g. hives, nettle rash, blistering or peeling of the skin.

If you start to itch or get a rash, STOP taking amoxicillin and tell your doctor immediately.

- Convulsions may occur in patients on high doses or with kidney problems
- Notice your urine becoming darker or your faeces becoming paler
- Notice your skin or the white of your eyes turning yellow (jaundice)
- Difficulty or discomfort in passing urine or having cloudy urine

The following symptoms are less serious but you may wish to discuss them with your doctor or pharmacist if they become troublesome or last a long time.

Common side effects of amoxicillin (i.e. more than 1 in 100 people):

- Nausea (feeling sick) or diarrhoea

Uncommon side effects (i.e. between 1 in 100 and 1 in 1,000 people):

- Vomiting

Very rare side effects (i.e. less than 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.
- Tooth discolouration. The colour usually returns to normal with brushing.
- Blackening of the tongue
- Inflammation of the kidney
- Excessive body movements (hyperkinesia) or dizziness
- Reduction (reversible) in blood cell counts including anaemia (a reduction in the body's red blood cells or haemoglobin which may be characterised by feeling weak or light-headed) or a longer time taken for blood to clot.
- Crystalluria (forming of crystals in the urine)

Not known (frequency cannot be estimated from available data)

- Meningitis (signs may include stiff neck, fever and vomiting)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE AMOXICILLIN

KEEP ALL MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use this medicine after the expiry date which is printed on the pack. This medicine should be used within 14 days of the date dispensed. Store below 25°C in a dry place, away from direct light.

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

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