

APO-Amoxicillin Suspension

Amoxicillin (as trihydrate)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before giving your child this medicine. Ask your doctor or pharmacist if you do not understand anything or are worried about your child taking this medicine.

This leaflet answers some common questions about amoxicillin.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. Some more recent information on the medicine may be available. Speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

All medicines have risks and benefits. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have.

Keep this leaflet with the medicine. You may want to read it again.

What this medicine is used for

The name of your child's medicine is APO-Amoxicillin Suspension. It contains a penicillin called amoxicillin (as trihydrate) as the active ingredient.

It is an antibiotic which used to treat infections in different parts of the body caused by bacteria.

Amoxicillin can also be used to prevent infection.

Amoxicillin will not work against infections caused by viruses such as colds or the flu.

How it works

Amoxicillin is an antibiotic that belongs to a group of medicines called penicillins. These antibiotics work by killing the bacteria that are causing your child's infection.

Ask your doctor if you have any questions about why this medicine has been prescribed for your child.

Your doctor may have prescribed amoxicillin for another reason.

This medicine is available only with a doctor's prescription.

There is no evidence that this medicine is addictive.

Use in children

Amoxicillin suspension is the most suitable form of amoxicillin to give to children.

If you are an adult and you are taking this suspension, you should also read the leaflet about Amoxicillin capsules.

Before you give this medicine

When your child must not take it

This medicine must not be taken if your child has had an allergic reaction to:

- amoxicillin
- other penicillins or cephalosporins
- any of the ingredients listed near the end of this leaflet.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue, throat or other parts of the body, muscle pain or tenderness, joint pain or rash, itching or hives on the skin.

This medicine must not be taken after the expiry date (EXP) printed on the pack.

If this medicine is taken after the expiry date has passed, it may not work as well.

This medicine must not be taken if the packaging is torn or shows signs of tampering or if it does not look quite right.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether your child should start taking amoxicillin, talk to your doctor or pharmacist.

Before your child starts to take it

Tell your doctor if:

1. **Your child is allergic to:**

- any other medicines
 - any other substances, such as foods, preservatives or dyes
2. **Your child has ever had an allergic reaction (such as a rash) to any antibiotics in the past.**
 3. **Your child has or has had any medical conditions, especially the following:**
 - glandular fever (mononucleosis)
 - blood disorders such as leukaemia
 - liver or kidney problems

If you have not told your doctor about any of the above, tell them before your child starts taking amoxicillin.

Taking other medicines

Tell your doctor or pharmacist if your child is taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and amoxicillin may interfere with each other. These include:

- medicines used to treat gout (eg probenecid or allopurinol)
- other antibiotics (e.g. tetracyclines)

These medicines may be affected by amoxicillin or may affect how well it works. Your child may need different amounts of medicine, or he/she may need to take different medicines.

Your doctor and pharmacist will advise you. They will tell you if your child is taking any of these medicines. They may also have more information on medicines to be careful with or avoid while taking amoxicillin.

How to give this medicine

Follow all directions from your doctor or pharmacist carefully.

They may be different to the information in this leaflet.

If you do not understand any written instructions, ask your doctor or pharmacist for help.

How much to give

Your doctor or pharmacist will tell you how much liquid you will need to give. This depends on your child's condition and whether or not they are taking any other medicines.

The usual dose of amoxicillin suspension is one dose three times a day. The dose may vary according to your child's weight.

How to give it

Shake the suspension in the bottle well before measuring out the dose in a suitable measure. Make sure that the whole dose is swallowed each time.

When to give it

Give it at about the same time each day.

Giving the medicine at the same time each day will have the best effect. It will also help you remember when to give it.

Space the doses as evenly as possible throughout the day.

For example, if your child is taking amoxicillin three times a day, give a dose about every eight hours.

Amoxicillin can be taken with or without food. The effects of amoxicillin are not changed by food.

How long to give it for

Continue giving amoxicillin to your child until your doctor says so.

Do not stop giving this medicine to your child because he/she is feeling better.

If the full course prescribed by your doctor is not completed, the infection may not clear completely or it may return.

Make sure you have enough to last over weekends and holidays.

If you forget to give it

If it is almost time for your child's next dose, skip the dose they

missed and give the next dose when you are meant to.

Otherwise, give it as soon as you remember, and then go back to giving the doses as you would normally.

Do not give a double dose to make up for the dose that was missed.

This may increase the chance of your child getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to give the doses, ask your pharmacist for some hints.

If your child takes too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 for Australia) or go to the Accident and Emergency Department at the nearest hospital, if you think that your child or anyone else may have taken too much amoxicillin.

Do this even if there are no signs of discomfort or poisoning.

Your child may need urgent medical attention.

If your child takes too much amoxicillin, they may feel sick or get diarrhoea.

While your child is taking this medicine

Things you must do

Tell your doctor if:

1. **The symptoms of your child's infection do not improve within a few days, or if they become worse.**
2. **Your child develops itching with swelling or skin rash or difficulty breathing. Stop giving this medicine and contact your doctor immediately.**
3. **Your child gets severe diarrhoea. Tell your doctor, pharmacist or nurse immediately. Do this even if it**

occurs several weeks after your child stopped taking amoxicillin.

Diarrhoea may mean that your child has a serious condition affecting the bowel. They may need urgent medical care.

Do not give any anti-diarrhoea medicine without first checking with your doctor.

4. Your child gets a sore white mouth or tongue while taking or soon after stopping amoxicillin, or if your daughter gets vaginal itching or discharge

This may mean they have a fungal infection called thrush. Sometimes the use of amoxicillin allows fungi to grow and the above symptoms to occur. Amoxicillin does not work against fungi.

5. Your child is about to have any blood tests.

6. Your child is about to start taking any other new medicine.

Tell any other doctors, dentists, and pharmacists who are treating your child that they are taking amoxicillin.

Keep any appointments with your doctor.

Your doctor may want to do tests to make sure the medicine is working and to prevent side effects.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to your child's.

Do not give this medicine to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop giving your child this medicine, or change the dosage, without checking with your doctor.

Side effects

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time,

they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for your child.

Tell your doctor or pharmacist as soon as possible if your child does not feel well while they are taking amoxicillin.

Ask your doctor or pharmacist to answer any questions you may have.

Following is a list of possible side effects. Do not be alarmed by this list. Your child may not experience any of them.

Tell your doctor or pharmacist if you notice your child has any of the following and they are troublesome or ongoing:

- oral thrush - white and sore tongue and mouth
- vaginal thrush - sore and itchy vagina and/or discharge
- diarrhoea
- nausea (feeling sick), indigestion or vomiting
- discoloured teeth. This usually goes away with extra brushing.

The above list includes the more common side effects. Mostly, these are mild.

Tell your doctor as soon as possible if you notice your child has any of the following:

- itching or any type of skin rash
- unusual bleeding or bruising
- yellowing of the skin or eyes
- dark urine or pale stools
- difficulty or pain on passing urine
- severe diarrhoea
- feeling hyperactive or having trouble concentrating.

These may be serious side effects.

Your child may need medical attention. Most of these side effects are rare

If any of the following happen, stop giving this medicine and either tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- allergic reaction including wheezing, fainting, swelling of

limbs, face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing.

These are very serious side effects. Your child may need urgent medical attention or hospitalisation.

Tell your doctor immediately if your child develops any of the following side effects, even if they occur several weeks after your child has stopped taking amoxicillin:

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may also be bloody
- fever, in combination with one or both of the above.

These are rare but serious side effects. Your child may have a serious condition affecting the bowel. Therefore, he/she may need urgent medical attention. This side effect is rare.

Do not give any anti-diarrhoea medicine without checking with your doctor first.

Other side effects not listed above may occur in some patients.

Tell your doctor or pharmacist if you notice anything that is making your child feel unwell.

Ask your doctor or pharmacist if you don't understand anything in this list.

Storage and disposal

Storage

Keep amoxicillin suspension in its original bottle until it is time to give it.

If you put the suspension in a different container it may not keep well.

Keep this medicine in a refrigerator; do not freeze it.

Do not use any suspension that is left after 14 days.

Do not store this medicine, or any other medicine, in the bathroom or near a sink.

Do not leave it on a window sill or in the car on hot days.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop giving this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your child's condition.

Product description

What APO-Amoxicillin Suspension looks like

APO-Amoxicillin Suspension when reconstituted by the pharmacist forms a 100 mL orange suspension, and is available in the following strengths:

- 125 mg/5 mL
- 250 mg/5 mL

Ingredients

Active Ingredient:

The suspension contains either 125 mg or 250 mg of amoxicillin (as trihydrate) in every 5 mL.

It also contains the following inactive ingredients:

- sorbitol
- sunset yellow FCF
- tutti frutti flavour (PI 183)
- xanthan gum
- sodium citrate dihydrate
- colloidal anhydrous silica

- saccharin sodium

Allergen information

APO-Amoxicillin Suspension contains saccharin.

APO-Amoxicillin Suspension contains sorbitol. The 125 mg/5 mL strength contains 18 g sorbitol in 120 mL reconstituted suspension. The 250 mg/5 mL strength contains 7.2 g sorbitol in 60 mL reconstituted suspension. Products containing sorbitol may have a laxative effect or cause diarrhoea.

APO-Amoxicillin 125 mg/5 mL Suspension contains 1.14 mg sodium in 1 mL reconstituted suspension.

APO-Amoxicillin Suspension does not contain lactose, sucrose, gluten or tartrazine.

Australian Registration Numbers

APO-Amoxicillin
125 mg/5 mL Suspension
Bottle: AUST R 137882

APO-Amoxicillin
250 mg/5 mL Suspension
Bottle: AUST R 137883

Sponsor

Arrotex Pharmaceuticals Pty Ltd
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