

AMOXYCILLIN SANDOZ®

Amoxicillin Trihydrate tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Amoxicillin Sandoz.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Amoxicillin Sandoz against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Amoxicillin Sandoz is used for

The name of your medicine is Amoxicillin Sandoz. It contains the active ingredient amoxicillin trihydrate.

Amoxicillin is an antibiotic used in the treatment of bacterial infections.

Amoxicillin Sandoz belongs to a group of antibiotics called penicillins. These antibiotics work by killing the bacteria that are causing your infection.

Amoxicillin Sandoz is used for the treatment of chest infections.

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

Your doctor may have prescribed Amoxicillin Sandoz for another reason. Ask your doctor if you have any questions about why Amoxicillin Sandoz has been prescribed for you.

Amoxicillin Sandoz is available only with a doctor's prescription.

Amoxicillin Sandoz is not addictive.

Before you take Amoxicillin Sandoz

When you must not take it

Do not take Amoxicillin Sandoz if:

- **you have an allergy to amoxicillin, any other penicillins or any of the ingredients listed at the end of this leaflet**
- **you have had a serious allergic reaction to any β -lactam antibiotics in the past (e.g. penicillins, cephalosporins carbapenem or monobactam). These are another group of antibiotics similar to penicillins**

You may have an increased chance of being allergic to Amoxicillin Sandoz if you are allergic to cephalosporins. Some of the symptoms of an allergic reaction may include wheezing, shortness of breath; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; faintness; skin rash, itching or hives.

Do not take Amoxicillin Sandoz after the expiry date printed on the pack has passed.

Do not take Amoxicillin Sandoz if the packaging is torn or shows signs of tampering or if the medicine shows any signs of deterioration.

If the medicine has expired, or is damaged or shows any signs of deterioration, return it to your pharmacist for disposal.

If you are not sure if you should start taking Amoxicillin Sandoz, contact your doctor.

Before you start to take it

Tell your doctor if:

1. **you have had any type of allergic reaction to any penicillin or cephalosporin medicines.**
You may have an increased chance of being allergic to Amoxicillin Sandoz if you are allergic to any penicillins or cephalosporins.

2. **you have any allergies to:**

- any other medicines
- any other substances such as foods, preservatives or dyes

3. **you are pregnant or intend to become pregnant.**

Your doctor will discuss the possible risks and benefits of using Amoxicillin Sandoz during pregnancy.

4. **you are breast-feeding or intend to breast-feed.**

Amoxicillin Sandoz passes into breast milk. No detrimental effects for the breast-fed infant have been reported after taking amoxicillin. Amoxicillin can be used during breast-feeding. However, breast-feeding must be stopped if gastrointestinal disorders (diarrhoea, candidosis or skin rash) occur in the new born. Your doctor will discuss the risks and benefits of taking Amoxicillin Sandoz when breast-feeding.

5. **you have or have had any medical conditions, including:**

- asthma
- kidney problems
- liver problems
- lymphatic leukaemia
- glandular fever
- diabetes
- seizures history
- stomach or bowel problems
- a history of allergic problems, including hay fever.

Taking other medicines

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

Some medicines may interfere with Amoxicillin Sandoz. These include:

- medicines used to treat gout (e.g. probenecid or allopurinol)
- digoxin, a medicine used to treat heart failure
- medicines used to prevent blood clots from the coumarin class (e.g. warfarin)
- methotrexate, a medicine used to treat arthritis and some types of cancers

- oral contraceptives (birth control pills)
- other antibiotics (e.g. tetracycline).

These medicines may be affected by Amoxicillin Sandoz or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Talk to your doctor about the need for an additional method of contraception while taking Amoxicillin Sandoz.

Some antibiotics may decrease the effectiveness of some birth control pills.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Amoxicillin Sandoz.

How to take Amoxicillin Sandoz

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you the dose of Amoxicillin Sandoz you will need to use each day.

The usual dose for Amoxicillin Sandoz is one tablet twice a day.

How to take it

Take Amoxicillin Sandoz with a glass of water.

When to take it

In order for Amoxicillin Sandoz to be most effective, it should be taken at the same times each day. Your doctor or pharmacist can advise you on a dosing schedule if you are unsure.

Amoxicillin Sandoz can be taken with or without food.

How long to take it

Continue taking Amoxicillin Sandoz until you finish the tablets or for as long as your doctor recommends.

Keep taking this medicine for the full course of treatment, even if you begin to feel better after a few days.

If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.

Check with your doctor if you are not sure how long you should be taking Amoxicillin Sandoz.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

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

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Amoxicillin Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Amoxicillin Sandoz, you may experience symptoms such as diarrhoea, nausea, vomiting or stomach cramps.

While you are taking Amoxicillin Sandoz

Things you must do

If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.

If you develop itching, swelling, a skin rash or difficulty in breathing while you are taking Amoxicillin Sandoz, do not take any more Amoxicillin Sandoz and tell your doctor immediately.

If you get severe diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after Amoxicillin Sandoz has been stopped.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any diarrhoea medicine without first checking with your doctor.

If you get a sore white mouth or tongue while taking or soon after stopping Amoxicillin Sandoz, tell your doctor. Also tell your doctor if you get vaginal itching or discharge.

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

If you become pregnant while taking Amoxicillin Sandoz, tell your doctor immediately.

If you have to test your urine for sugar while you are using Amoxicillin Sandoz, make sure your doctor knows which type of test you use.

Amoxicillin Sandoz may affect the results of some of these tests.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Amoxicillin Sandoz.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Amoxicillin Sandoz.

Things you must not do

Do not stop taking your medicine because you are feeling better, unless advised by your doctor.

If you do not complete the full course prescribed by your doctor, all of the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear completely or it may return.

Do not give Amoxicillin Sandoz to anyone else, even if they have the same condition as you.

Do not use Amoxicillin Sandoz to treat any other complaints, unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how Amoxicillin Sandoz affects you.

Amoxicillin Sandoz may cause tiredness or dizziness in some people. Make sure you know how you react to Amoxicillin Sandoz before you drive a car, operate machinery or do anything else that may be dangerous if you are affected.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Amoxicillin Sandoz.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. The most commonly reported adverse drug reactions (ADRs) are diarrhoea, nausea and skin rash.

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

While you are taking Amoxicillin Sandoz

Tell your doctor if you notice any of the following and they worry you:

- oral thrush - white, furry, sore tongue and mouth
- vaginal thrush - sore and itchy vagina or discharge
- mild diarrhoea
- feeling sick (nausea), vomiting
- soreness of the mouth or tongue
- discoloration of the teeth (especially with the suspension). Usually the discoloration can be removed by teeth brushing
- headache, tiredness.

These side effects are usually mild.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- signs of anaemia such as looking pale, short of breath when exercising, dizziness
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bruising or bleeding more easily than normal
- dark coloured urine or blood in the urine
- passing more or less urine than is normal for you
- yellowing of the skin or eyes
- convulsions
- aching or swollen joints.
- a red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, neck.

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, stop taking Amoxicillin Sandoz and tell your doctor immediately, or go to Accident and Emergency at the nearest hospital:

- any skin rash, itching or hives or blistering or peeling of the skin
- wheezing, shortness of breath or difficulty breathing
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- severe abdominal cramps or stomach cramps
- excessive abnormal muscle movements
- watery and severe diarrhoea, which may also be bloody.

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

After finishing it

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment:

- 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.

You may have a serious condition affecting your bowel, and you may need urgent medical attention. These are rare but serious side effects.

Do not take any diarrhoea medicine without first checking with your doctor.

Other side effects not listed in this leaflet may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Amoxicillin Sandoz

Storage

- Keep your Amoxicillin Sandoz in its original container, in a safe place out of the reach of children.
- Store Amoxicillin Sandoz tablets in a cool dry place, away from sunlight, where the temperature stays below 25°C.
- Do not store your medicine in the bathroom or near a sink. Heat and dampness can destroy some medicines.
- Do not leave your medication in a car or on a window sill.

Disposal

If your doctor tells you to stop taking Amoxicillin Sandoz, or the medicine has passed its expiry date, ask your pharmacist what to do with any medicine left over.

Product description

What it looks like

Amoxicillin Sandoz are white to cream-coloured, oval, biconvex tablets scored on both sides and supplied in blister packs of 2 or 14 tablets in a cardboard carton.

Ingredients

Amoxicillin Sandoz tablets contain 1000 mg amoxicillin (as amoxicillin trihydrate) as the active ingredient.

The tablets also contain the following inactive ingredients:

- magnesium stearate
- cellulose - microcrystalline
- povidone
- sodium starch glycollate
- titanium dioxide
- talc - purified
- hypromellose.

Supplier

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel: 1800 726 369

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1000mg Tablets: AUST R 98758 (Blisters)

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