Amoxycillin Sandoz®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Amoxycillin Sandoz?

Amoxycillin Sandoz contains the active ingredient amoxicillin (as amoxicillin trihydrate). Amoxycillin Sandoz is used to treat a range of infections caused by bacteria.

For more information, see Section 1. Why am I using Amoxycillin Sandoz? in the full CMI.

2. What should I know before I use Amoxycillin Sandoz?

Do not use if you have ever had an allergic reaction to Amoxycillin Sandoz or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Amoxycillin Sandoz? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Amoxycillin Sandoz and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Amoxycillin Sandoz?

- The usual dose of Amoxycillin Sandoz is one dose taken three times a day.
- Amoxycillin Sandoz doses should be spaced evenly throughout the day e.g. every eight hours if taking it three times a day.
- Swallow Amoxycillin Sandoz 250 mg and 500 mg capsules whole with a glass of water. It can be taken with or without food.
- Keep taking Amoxycillin Sandoz until the course is finished or for as long as your doctor tells you.

More instructions can be found in Section 4. How do I use Amoxycillin Sandoz? in the full CMI.

5. What should I know while using Amoxycillin Sandoz?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Amoxycillin Sandoz. • Tell your doctor if, for any reason, you have not taken your medicine exactly as directed. • Tell your doctor immediately if you develop severe itching or swelling, a skin rash, or severe diarrhoea.
Things you should not do	• Do not give this medicine to anyone else, even if their symptoms seem similar to yours. • Do not use Amoxycillin Sandoz to treat any other complaints unless your doctor says to.
Looking after your medicine	• Keep your medicine in its original container, in a safe place out of reach of children. • Keep it in a cool dry place, away from moisture or heat, where the temperature stays below 25°C.

For more information, see Section 5. What should I know while using Amoxycillin Sandoz? in the full CMI.

6. Are there any side effects?

Mild side effects of taking Amoxycillin Sandoz include diarrhoea, soreness of the mouth or tongue, or overgrowth of yeast infections (thrush).
Serious side effects include itching; rash; unusual bleeding or bruising; yellowing of the skin or eyes; dark urine or pale stools; difficulty or pain on passing urine; severe diarrhoea; excessive abnormal muscle movements; dizziness or convulsions; or a red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, or neck. Other serious side effects include an allergic reaction. Signs of this include wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives), or fainting.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Amoxycillin Sandoz®

Active ingredient(s): *amoxicillin trihydrate capsules and suspension*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Amoxycillin Sandoz. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Amoxycillin Sandoz.**

Where to find information in this leaflet:

1. Why am I using Amoxycillin Sandoz?
2. What should I know before I use Amoxycillin Sandoz?
3. What if I am taking other medicines?
4. How do I use Amoxycillin Sandoz?
5. What should I know while using Amoxycillin Sandoz?
6. Are there any side effects?
7. Product details

1. Why am I using Amoxycillin Sandoz?

Amoxycillin Sandoz contains the active ingredient amoxicillin (as amoxicillin trihydrate). Amoxycillin Sandoz belongs to a group of antibiotic medicines called penicillins.

Amoxycillin Sandoz is used to treat a range of infections caused by bacteria. These may be infections of the chest (pneumonia), tonsils (tonsillitis), sinuses (sinusitis), urinary and genital tract, skin and fleshy tissues.

Amoxycillin Sandoz works by killing the bacteria that cause these infections.

Amoxycillin Sandoz can also be used to prevent infection.

Ask your doctor if you have any questions about why Amoxycillin Sandoz has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

2. What should I know before I use Amoxycillin Sandoz?

Warnings

Do not use Amoxycillin Sandoz if:

- you are allergic to penicillin or similar types of antibiotics such as cephalosporins. If you have ever had an allergic reaction (such as rash) when taking an antibiotic, you should tell your doctor before you take Amoxycillin Sandoz.
- you are allergic to amoxicillin or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue, or any other parts of the body; rash, itching or hives on the skin.
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have any other medical conditions, especially the following:
  - glandular fever (mononucleosis)
  - blood disorders
  - kidney or liver problems

  (your dose may need to be changed or you may need to be given an alternate medicine)
- take any medicines for any other condition.
- have ever had an allergic reaction (such as a rash) to any antibiotics in the past.
- have had any allergy to any other medicines, or any other substances, such as foods, preservatives, or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Amoxycillin Sandoz may be used during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Amoxycillin Sandoz can pass to your baby from breast milk.

3. What if I am taking other medicines?

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

Some medicines may interfere with Amoxycillin Sandoz and affect how it works. These include:

- medicines used to treat gout e.g. probenecid or allopurinol.
- contraceptive pill (as with other antibiotics, you may need to use extra birth control methods e.g. condoms)
- other antibiotics
- anticoagulants (used to prevent blood clots) such as warfarin
- methotrexate, a medicine used to treat arthritis and some types of cancers

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Amoxycillin Sandoz.

Amoxycillin Sandoz may influence the results of some laboratory tests.

4. How do I use Amoxycillin Sandoz?

How much to take/give

Take/Give Amoxycillin Sandoz as directed by your doctor.

Your doctor will tell you the dose of Amoxycillin Sandoz you will need to use each day. This depends on the condition being treated and whether any other medicines are being used.

The usual dose is one dose taken three times a day. The doses should be spaced evenly throughout the day e.g. every eight hours if taking it three times a day.

How to take/give Amoxycillin Sandoz

Amoxycillin Sandoz Capsules:

Swallow Amoxycillin Sandoz capsules whole with a glass of water.

Amoxycillin Sandoz can be taken with or without food.

Amoxycillin Sandoz Suspension:

The suspension will be prepared by your pharmacist who checks the seal prior to reconstitution. Shake the bottle well and accurately measure the dose with a measuring spoon. Your pharmacist will explain how many millilitres of suspension will be needed to receive the correct dose.

Do not use the reconstituted suspension if the colour is not off-white.

Shaking the bottle and using a measuring spoon will make sure that you get the correct dose.

How long to take/give Amoxycillin Sandoz for

Keep taking/giving Amoxycillin Sandoz until the course is finished or for as long as your doctor tells you.

Do not stop taking/giving Amoxycillin Sandoz just because you or your child feels better as the infection may return.

Do not stop taking/giving Amoxycillin Sandoz or change the dose without first checking with your doctor.

If you forget to use Amoxycillin Sandoz

If you miss your/your child's dose at the usual time, take/give it as soon as you remember. Then go back to taking/giving it as directed by your doctor.

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

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

Do not take/give two doses within an hour or so of each other.

Taking more than the prescribed dose can increase the chance of unwanted side effects.

If you use too much Amoxycillin Sandoz

If you think that you have used too much Amoxycillin Sandoz, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Amoxycillin Sandoz?

Things you should do

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

Tell your doctor or pharmacist you are taking Amoxycillin Sandoz before starting any other prescribed medicine.

Some medicines may affect the way other medicines work.

Call your doctor straight away if you:

- develop itching, swelling or a skin rash when you are taking Amoxycillin Sandoz. Do not take any more Amoxycillin Sandoz.
- develop severe diarrhoea when taking Amoxycillin Sandoz. Do not take any medication to stop the diarrhoea (e.g. Lomotil or Imodium).

Remind any doctor, dentist or pharmacist you visit that you are using Amoxycillin Sandoz.

Things you should not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use Amoxycillin Sandoz to treat any other complaints unless your doctor says to.

Looking after your medicine

Keep your medicine in its original container, in a safe place out of reach of children.

Keep Amoxycillin Sandoz capsules or the suspension in a cool dry place, away from moisture or heat, where the temperature stays below 25°C.

For example, do not store it:

- in the bathroom or near a sink, or
- in the car on a hot day.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

Discard any unused suspension after 14 days or after the expiry date placed by your pharmacist on the label of the bottle during the preparation of the suspension.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• diarrhoea (several loose bowel movements per day), indigestion, feeling sick or being sick. • soreness of the mouth or tongue • overgrowth of yeast infections (thrush)	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• itching, rash • unusual bleeding or bruising • yellowing of the skin or eyes • dark urine or pale stools • difficulty or pain on passing urine • severe diarrhoea • excessive abnormal muscle movements • dizziness or convulsions • a red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, neck.	**Tell your doctor immediately if you experience any of these serious side effects.**
Signs of allergic reaction: • Wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting.	**STOP taking Amoxycillin Sandoz and contact your doctor immediately or go to the emergency department of your nearest hospital if you experience any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Amoxycillin Sandoz contains

Amoxycillin Sandoz Capsules:

Active ingredient (main ingredient)	amoxicillin (as amoxicillin trihydrate)
Other ingredients (inactive ingredients)	magnesium stearate microcrystalline cellulose gelatin iron oxide yellow titanium dioxide.

Amoxycillin Sandoz Suspension:

Active ingredient (main ingredient)	amoxicillin (as amoxicillin trihydrate)
Other ingredients (inactive ingredients)	anhydrous citric acid sodium benzoate aspartame purified talc guar gum sodium citrate anhydrous silicon dioxide lemon flavouring orange flavouring peach-apricot flavouring
Potential allergens	benzoates, aspartame

Do not take this medicine if you are allergic to any of these ingredients.

What Amoxycillin Sandoz looks like

Amoxycillin Sandoz 250 mg Capsules - opaque yellow hard gelatin capsules. Available in blisters packs of 20 capsules (Aust R 63332).

Amoxycillin Sandoz 500 mg Capsules - opaque yellow hard gelatin capsules. Available in blisters packs of 20 capsules (Aust R 63333).

Amoxycillin Sandoz 125 mg/5 mL Suspension - After mixing, the suspension is white to slightly yellowish. Available in 100 mL bottle (Aust R 93721).

Amoxycillin Sandoz 250 mg/5 mL Suspension - After mixing, the suspension is white to slightly yellowish. Available in 100 mL bottle (Aust R 93720).

Who distributes Amoxycillin Sandoz

Sandoz Pty Ltd
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Australia

Tel 1800 726 369

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