

Azithromycin 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 taking Azithromycin Sandoz?

Azithromycin Sandoz contains the active ingredient azithromycin. Azithromycin Sandoz is used to treat infections in different parts of the body caused by bacteria.

For more information, see Section [1. Why am I taking Azithromycin Sandoz?](#) in the full CMI.

2. What should I know before I take Azithromycin Sandoz?

Do not use if you (or your child) have ever had an allergic reaction to azithromycin or other antibiotics that are the same type, or any of the ingredients listed at the end of the CMI. Your doctor will know which antibiotics are the same type as Azithromycin Sandoz. Azithromycin Sandoz tablets contain lactose.

Talk to your doctor if you (or your child) have kidney, liver or heart problems including abnormalities of the rhythm; muscle weakness; low levels of potassium or magnesium in your blood; take any other medicines; if you are pregnant, or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take Azithromycin Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Azithromycin 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 take Azithromycin Sandoz?

Your doctor will decide how much Azithromycin Sandoz you or your child should take, it will depend on the type of infection, or child's bodyweight.

More instructions can be found in Section [4. How do I take Azithromycin Sandoz?](#) in the full CMI.

5. What should I know while taking Azithromycin Sandoz?

Things you should do	<ul style="list-style-type: none">• Tell your doctor if the symptoms of the infection do not improve within a few days or they become worse; you have chest pain; shortness of breath; dizziness; severe diarrhoea; sore white mouth or tongue; you have vaginal itching or discharge; you become pregnant or are breastfeeding.• Talk to your doctor about the need for additional method of contraception.• Tell your doctor immediately if during treatment with Azithromycin Sandoz your baby develops irritability with feeding or starts vomiting.• Tell any other doctor or dentist you visit that you (or your child) are taking Azithromycin Sandoz.• For more information on "Things you should do" can be found in Section 5 in the full CMI.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine or lower the dosage without checking with your doctor.• Do not take Azithromycin Sandoz to treat any other medical complaints unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or using any machines or tools until you know how Azithromycin Sandoz affects you. Azithromycin Sandoz may cause dizziness in some people.
Looking after your medicine	<ul style="list-style-type: none">• Store in original carton at below 25°C until ready for use.

For more information, see Section [5. What should I know while taking Azithromycin Sandoz?](#) in the full CMI.

6. Are there any side effects?

Side effects of this medicine may include oral/vaginal thrush; nausea; vomiting; loss of appetite; fever; diarrhoea; stomach pain; constipation; indigestion; dizziness; headache; spinning sensation; drowsiness; fatigue; restlessness; aggression; nervousness; agitation; anxiety; chest pain; palpitations; sweat; shortness of breath; wheezing; convulsions; fainting; rash, itching or hives; swelling of face, lips, tongue or body; sunburn; decreased sensitivity especially skin; blisters or ulcers on skin, mouth or airways; muscle pain; numbness or weakness; trouble speaking, understanding or walking; loss of balance; lack of coordination; abnormal hearing; altered vision, taste/smell; dark urine or blood in urine or bowel motions; jaundice.

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.

Azithromycin Sandoz®

Active ingredient(s): *azithromycin (as dihydrate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Azithromycin 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 Azithromycin Sandoz.**

Where to find information in this leaflet:

- [1. Why am I taking Azithromycin Sandoz?](#)
- [2. What should I know before I take Azithromycin Sandoz?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take Azithromycin Sandoz?](#)
- [5. What should I know while taking Azithromycin Sandoz?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking Azithromycin Sandoz?

Azithromycin Sandoz contains the active ingredient azithromycin which is an antibiotic. It belongs to a group of medicines called azalides. The azalides are a sub-class of a group of antibiotics called macrolides.

Azithromycin Sandoz is used to treat infections in different parts of the body caused by bacteria.

It is commonly used to treat Chlamydia.

Azithromycin Sandoz works by killing or stopping the growth of bacteria causing your infection.

Azithromycin Sandoz will not work against viral infections such as colds or flu.

Your doctor may have prescribed it for another reason.

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

2. What should I know before I take Azithromycin Sandoz?

Warnings

Do not use Azithromycin Sandoz if you are allergic to:

- azithromycin
- any of the ingredients listed at the end of this leaflet
- any other macrolide or ketolide antibiotics (e.g., clarithromycin, erythromycin, roxithromycin, telithromycin). Your doctor will know which antibiotics are the same type as Azithromycin Sandoz
- lactose

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

Do not use Azithromycin Sandoz if:

- the packaging is torn or shows signs of tampering
- the expiry date printed on the pack has passed.

Check with your doctor if you have ever had:

- liver problems
- kidney problems
- heart problems, including abnormalities of the rhythm
- diabetes
- hereditary fructose intolerance, glucose-galactose malabsorption or saccharise-isomaltase deficiency
- cystic fibrosis
- muscle weakness
- low levels of potassium or magnesium in your blood.

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.

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

Your doctor can discuss with you the risks and benefits involved.

This medicine is available only with a doctor's prescription. Azithromycin Sandoz is not addictive.

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 Azithromycin Sandoz or increase the risk of side effects. These include:

- antacids (medicines used to treat indigestion)
- colchicine (a medicine used to treat gout)
- coumarin-type oral anti-coagulants (a medicine used to prevent blood clots)
- ciclosporin (a medicine used to prevent organ transplant rejection or to treat certain problems with the immune system)
- atorvastatin (a medicine used to lower cholesterol)
- digoxin (a medicine used to treat abnormal heart rhythm or heart failure)

- ergot derivatives (such as ergotamine, which is used to treat migraines)
- terfenadine or astemizole (medicines used to treat allergies and hay fever)
- zidovudine, a medicine used to treat patients with AIDS
- some medicines used to treat heart rhythm problems (heart arrhythmia) such as amiodarone, disopyramide, ibutilide and sotalol
- antipsychotic medicines used to treat schizophrenia or bipolar mania such as haloperidol, quetiapine and risperidone
- medicines used to treat depression (antidepressants) such as fluoxetine, sertraline and venlafaxine
- fluoroquinolone antibiotics such as ciprofloxacin, lomefloxacin, moxifloxacin and norfloxacin
- oral contraceptives (birth control pills). Some side effects from Azithromycin Sandoz may interfere with effectiveness of birth control pills.

These medicines may be affected by Azithromycin Sandoz or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Talk to your doctor about the need for additional contraception while taking Azithromycin Sandoz.

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

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking Zithromax.

4. How do I take Azithromycin Sandoz?

How much to take

The doctor will decide what dose of Azithromycin Sandoz is needed depending on certain factors such as the type of infection and bodyweight of your child.

The usual dose to treat Chlamydia is two 500 mg tablets taken as a single dose.

For other infections Azithromycin Sandoz is usually taken once a day. Sometimes the dose is taken once a week. Your doctor will decide the right dose for you.

Your pharmacist will explain how to use it if you are not sure.

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

They 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 long to take Azithromycin Sandoz

Continue taking Azithromycin Sandoz until you finish the pack or until your doctor recommends.

Do not stop taking it because you are feeling better.

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

If you are not sure how long you should be taking Azithromycin Sandoz, check with your doctor.

When to take Azithromycin Sandoz

Azithromycin may be taken with or without food.

If you are taking an antacid, take it at least one hour before or two hours after your Azithromycin Sandoz dose.

This will avoid any possible effect of the antacid on the absorption of Azithromycin Sandoz.

How to take Azithromycin Sandoz

Swallow the tablets whole with liquid.

If you forget to use Azithromycin Sandoz

If you are taking Azithromycin Sandoz for three days or longer and you miss a dose, take it as soon as you remember (within a 24-hour period), then continue as normal.

Do not try to make up for missed doses by taking more than one dose at a time.

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

If you have trouble remembering to take your Azithromycin Sandoz, ask your pharmacist for some hints

If you use too much Azithromycin Sandoz

If you think that you have used too much Azithromycin 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. You may need urgent medical attention.

If you take too many tablets, you may get an upset stomach, diarrhoea or skin rashes.

5. What should I know while taking Azithromycin Sandoz?

Things you should do

Call your doctor straight away if:

- the symptoms of your infection do not improve within a few days, or if they become worse
- you have chest pain, shortness of breath, sudden dizziness, light-headedness or numbness in the face, arm, or leg

- you have severe diarrhoea. Do this even if it occurs several weeks after Azithromycin 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.

- you have a sore, white mouth or tongue while taking, or soon after stopping Azithromycin Sandoz
- you have vaginal itching or discharge.

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

- your baby develops irritability with feeding or starts vomiting.

This may be a sign of a stomach disorder in the infant.

- If you become pregnant while taking Azithromycin Sandoz.

If you are about to start any new medicines, tell your doctor and pharmacist that you are taking Azithromycin Sandoz.

Tell any other doctor or dentist you visit that you are taking Azithromycin Sandoz.

Things you should not do

- Do not stop taking Azithromycin Sandoz or lower the dosage without checking with your doctor.

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

- Do not give Azithromycin Sandoz to anyone else, even if they have the same condition as you
- Do not use Azithromycin Sandoz to treat any other medical complaints unless your doctor tells you to
- Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting with a pharmacist.

Things to be careful of

Protect your skin when you are in the sun, especially between 10am and 3pm.

Some macrolide antibiotics may cause your skin to be more sensitive to sunlight than it is normally. Exposure to sunlight may cause a skin rash, itching, redness or severe sunburn.

If outdoors, wear protective clothing and use a 30+ sunscreen. If your skin does appear to be burning tell your doctor immediately.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Azithromycin Sandoz affects you.

Azithromycin Sandoz may cause dizziness in some people.

Drinking alcohol

No information available.

Looking after your medicine

Keep Azithromycin Sandoz in its original packaging until it is time to use it. If you take Azithromycin Sandoz out of its packaging, it may not keep as well.

Keep your Azithromycin Sandoz in a cool, dry place where the temperature stays below 25°C.

Do not store Azithromycin Sandoz or any other medicine in the bathroom or near a sink. Do not leave it in the car or on a window sill. Heat and dampness can destroy some medicines.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

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

When to discard your medicine

If your doctor tells you to stop taking this medicine, or it has passed its expiry date, take it to any pharmacy for safe disposal.

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
<ul style="list-style-type: none"> • oral thrush - white, furry, sore tongue and mouth • vaginal thrush - sore and itchy vagina and/or white discharge • nausea • vomiting • loss of appetite • constipation • stomach pain • indigestion • wind • dizziness, spinning sensation • headache • tiredness • drowsiness • fatigue • restlessness • muscle or joint aches • rash • hearing loss or ringing in the ears 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> altered taste and smell. 	
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> diarrhoea, usually with blood and mucus, stomach pain and fever severe upper stomach pain, often with nausea and vomiting fast or irregular heart beat, palpitations chest pain sudden dizziness or light-headedness cold sweat sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing widespread body rash, fever and swollen lymph nodes symptoms of sunburn such as redness, itching, swelling or blistering which may occur more quickly than normal decreased feeling or sensitivity, especially in the skin signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers bleeding or bruising more easily than normal, reddish or purplish blotches under the skin dark urine or blood in the urine or bowel motions blisters or ulcers on the skin, in the mouth or airways that may occur after a period of fever yellowing of the eyes or skin, also called jaundice pain or discomfort in the jaw, neck, back, arm, leg or shoulder numbness or weakness in the face, arm, or leg trouble with speech, or understanding speech aggressive reaction, nervousness, agitation or anxiety problems with vision trouble walking, loss of balance, or lack of coordination fainting convulsions (fits). 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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

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.

Some of these side effects (for example certain liver conditions, and blood abnormalities) can only be found when your doctor does tests from time to time to check your progress.

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 with Azithromycin Sandoz.

- 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.

Azithromycin Sandoz can cause some bacteria, which are normally present in the bowel and normally harmless, to multiply and therefore cause the above symptoms. You may need urgent medical attention. However, this side effect is rare.

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

Ask your doctor or pharmacist if you don't understand anything in these lists.

Do not be alarmed by the lists of possible side effects. You may not experience any of them.

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 Azithromycin Sandoz contains

Active ingredient (main ingredient)	azithromycin (as dihydrate)
Other ingredients (inactive ingredients)	microcrystalline cellulose maize starch sodium starch glycollate – type A colloidal anhydrous silica magnesium stearate

	sodium lauryl sulfate lactose monohydrate hypromellose titanium dioxide macrogol 4000.
Potential allergens	lactose

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

What Azithromycin Sandoz looks like

Azithromycin Sandoz 500 mg - white to off-white, oval, film-coated tablet, plain on one side, with a breaking notch and 'A500' embossed on the other side. Available in blister packs of 2 or 3 tablets (Aust R 158292).

Not all presentations may be available in Australia.

Who distributes Azithromycin Sandoz

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

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