

Azithromycin Sandoz®

azithromycin dihydrate

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Azithromycin 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 this medicine 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 want to read it again.

WHAT AZITHROMYCIN SANDOZ IS USED FOR

This medicine is used to treat infections in different parts of the body caused by bacteria. It is commonly used to treat Chlamydia. It contains the active ingredient azithromycin.

Azithromycin belongs to a group of medicines called azalides. The azalides are a sub-class of a group of antibiotics called macrolides.

It 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.

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

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is not expected to affect your ability to drive a car or operate machinery.

BEFORE YOU TAKE AZITHROMYCIN SANDOZ

When you must not take it

Do not take this medicine if you have an allergy to:

- azithromycin, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description
- any other macrolide or ketolide antibiotics (e.g. clarithromycin, erythromycin, roxithromycin, telithromycin).

Some of the 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 take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- any liver problems
- any kidney problems
- any 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.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

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

If you have not told your doctor about any of the above, tell him/her before you start taking Azithromycin Sandoz.

Taking other medicines

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

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

- antacids (medicines used to treat indigestion)

- colchicine (a medicine used to treat gout)
- coumarin-type oral anti-coagulants (medicines used to prevent blood clots)
- ciclosporin (a medicine used to prevent organ transplant rejection or to treat certain problems with the immune system)
- digoxin (a medicine used to treat heart failure)
- ergot derivatives (such as ergotamine, which is used to treat migraines)
- terfenadine or astemizole (medicines used to treat allergies)
- zidovudine, a medicine used to treat patients with AIDS
- diphenoxylate, a medicine used to treat diarrhoea
- 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.

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.

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

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

Some antibiotics may decrease the effectiveness of some birth

control pills, although this has not been shown with Azithromycin Sandoz.

HOW TO TAKE AZITHROMYCIN SANDOZ

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, ask your doctor or pharmacist for help.

How much to take

The dose will depend on your infection.

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.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Azithromycin Sandoz may not work as well and your problem may not improve.

How to take it

Swallow the tablets whole with a full glass of water.

If you need to break Azithromycin Sandoz, hold the tablet with both hands and snap along the break line.

When to take Azithromycin Sandoz

This medicine may be taken with or without food.

If you need to take an antacid, take it at least 2 hours before or 2 hours after your dose of Azithromycin Sandoz.

This will avoid any possible effect of the antacid on the absorption of this medicine.

How long to take Azithromycin Sandoz

Continue taking your medicine until you finish the pack or for as long as your doctor tells you.

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

Do not stop taking it because you are feeling better.

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

If you forget to take it

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 take a double dose to make up for the dose that you missed.

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

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) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Azithromycin Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include an upset stomach, diarrhoea or skin rashes.

WHILE YOU ARE TAKING AZITHROMYCIN SANDOZ

Things you must do

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

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

If you have chest pain, shortness of breath, sudden dizziness, lightheadedness or numbness in the face, arm, or leg, tell your doctor, pharmacist or nurse immediately. You may need urgent medical attention.

If you get severe diarrhoea, tell your doctor, pharmacist or nurse immediately.

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.

Tell your doctor if you get a sore, white mouth or tongue while taking, or soon after stopping Azithromycin Sandoz. Tell your doctor if you get vaginal itching or discharge.

This may mean you have a yeast infection called thrush. Sometimes the use of this medicine allows yeast to grow and the above

symptoms to occur. Azithromycin Sandoz does not work against yeast.

Things you must not do

Do not stop taking your medicine 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 take Azithromycin Sandoz to treat any other complaints unless your doctor tells you to.

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

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.

SIDE EFFECTS

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

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

Tell your doctor or pharmacist 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 and/or white discharge)
- nausea (feeling sick), loss of appetite, vomiting, stomach pain, indigestion, wind, constipation, diarrhoea, loose bowel motions
- dizziness, headache, spinning sensation
- tiredness, drowsiness, fatigue
- muscle or joint aches
- rash
- hearing loss or ringing in the ears
- altered taste and smell
- visual impairment.

These are mild side effects of the medicine, and are short-lived.

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

- severe persistent diarrhoea (loose bowel motions)
- fast or irregular heart beat
- 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
- hives, itching or skin rash
- widespread body rash, fever and swollen lymph nodes
- aggressive reaction, nervousness, agitation or anxiety
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- blood in the urine or bowel motions

- severe upper stomach pain, often with nausea and vomiting.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

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

- 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
- blisters or ulcers on the skin, in the mouth or airways that may occur after a period of fever
- diarrhoea, usually with blood and mucus, stomach pain and fever
- yellowing of the eyes or skin, also called jaundice
- chest pain
- shortness of breath
- pain or discomfort in the jaw, neck, back, arm, or shoulder
- sudden dizziness or lightheadedness
- cold sweat
- numbness or weakness in the face, arm, or leg
- trouble speaking or understanding what others are saying
- problems with vision
- trouble walking, loss of balance, or lack of coordination
- fainting
- convulsions (fits).

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

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 stomach cramps

- watery and severe diarrhoea, which may 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.

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

Other side effects not listed above may also occur in some people.

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

AFTER TAKING AZITHROMYCIN SANDOZ

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine 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 on a window sill or in the car.

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 tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

Azithromycin Sandoz comes in one type of tablet:

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.

Not all presentations may be available in Australia.

Ingredients

Active ingredient:

- Azithromycin Sandoz 500 mg - 500 mg azithromycin (as dihydrate).

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.

This medicine contains lactose.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Sandoz Pty Ltd
100 Pacific Highway

North Sydney, NSW 2060

Australia

Tel 1800 726 369

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Australian Register Number

500 mg film-coated tablet: AUST R
158292 (blisters)

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