

APO-Azithromycin Tablets

Azithromycin dihydrate

Consumer Medicine Information

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

What is in this leaflet

This leaflet answers some common questions about azithromycin. 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 using 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 this medicine is used for

Azithromycin is used to treat infections in different parts of the body caused by bacteria, such as chlamydia. Azithromycin belongs to a group of medicines called macrolide antibiotics.

How it works

Azithromycin works by killing or stopping the growth of bacteria causing your infection. Azithromycin 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 this medicine for another reason.

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

This medicine is not addictive.

There is not enough information to recommend the use of azithromycin tablets in children.

Before you take this medicine

When you must not take it

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

- azithromycin
- macrolide antibiotics (e.g. clarithromycin, erythromycin, roxithromycin, telithromycin)
- any of the ingredients listed at the end of this leaflet

Some of the 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
- 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:

- liver or kidney problems
- heart problems, including heart rhythm abnormalities
- electrolyte disturbance, particularly low levels of potassium or magnesium in your blood
- myasthenia gravis

Tell your doctor if you have pneumonia and any of the following risk factors:

- cystic fibrosis
- infection occurring in hospital
- infection of the blood
- hospital admission
- elderly
- significant health problems (including immunodeficiency)

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

Do not take this medicine until you and your doctor have discussed the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

Tell your doctor 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 may interact with azithromycin. These include:

- antacids, used to treat indigestion
- colchicine (a medicine used to treat gout)
- medicines used to prevent blood clots
- ciclosporin, used to treat immune system problems
- digoxin, used to treat heart failure
- ergot derivatives (e.g. ergotamine, used to treat migraines)
- terfenadine or astemizole, used to treat allergies
- zidovudine, used to treat patients with AIDS
- lomotil, used to treat diarrhoea
- some medicines used to treat heart rhythm problems (e.g. amiodarone, disopyramide, ibutilide, sotalol)
- antipsychotic medicines (e.g. haloperidol, quetiapine, risperidone)
- medicines used to treat depression (e.g. fluoxetine, sertraline, venlafaxine)
- fluoroquinolone antibiotics (e.g. ciprofloxacin, lomefloxacin, moxifloxacin, norfloxacin)

These medicines may be affected by this medicine 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.

How to take this medicine

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

They may differ to 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 how much of this medicine you should take, depending on your condition and whether you are taking any other medicines.

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

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

How to take it

Swallow the tablets whole with liquid.

If you are taking an antacid (e.g., Gastrogel, Mylanta), take it at least one hour before or two hours after this medicine dose. This will avoid any possible effect of the antacid on the absorption of azithromycin.

When to take it

Take this medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

This medicine may be taken with or without food.

How long to take it for

Continue taking your medicine until you finish the pack or until your doctor says to. Do not stop taking it because you are feeling better.

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

If you forget to take it

If you are taking your medicine 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 missed doses.

This may increase the chance of you experiencing side effects.

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

If you have trouble remembering 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 your nearest hospital if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking this medicine

Things you must do

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

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

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

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

If you get severe diarrhoea, tell your doctor immediately. Do this even if it occurs several weeks after

you have stopped taking your medicine.

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 azithromycin, tell your doctor. Also tell your doctor if you get vaginal itching or discharge.

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

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may want to check your progress to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

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

Do not take your medicine to treat any other complaint unless your doctor tells you to.

Do not stop taking your medicine, or change the dosage, without first checking with your doctor.

If you do not complete the full course, 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.

Things to be careful of

Be careful driving or operating machinery until you know how this medicine affects you.

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 and pharmacist as soon as possible if you do not feel well while you are taking azithromycin.

This medicine helps most people with infections, but it may have unwanted side effects in a few people. 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 if you notice any of the following:

- 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
- dizziness, headache, spinning sensation
- tiredness, drowsiness, fatigue muscle or joint aches
- hearing loss or ringing in the ears
- altered taste and smell

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible and before you take your next dose of azithromycin 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
- 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 and you may need urgent medical attention.

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

- shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin (signs of an allergic reaction)
- 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
- convulsions (fits)

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

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

- severe stomach cramps
- watery and severe diarrhoea, which may be bloody

- fever, in combination with one or both of the above.

Azithromycin 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. This side effect is rare.

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

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

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

Storage and disposal

Storage

Keep your medicine in the pack until it is time to take it.

If you take your medicine out of its pack it may not keep well.

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

Do not store your medicine, 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 this medicine 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 leftover.

Product description

What it looks like

White, oval, biconvex film coated tablets engraved "APO" on one side and "AZ500" on the other side.

Bottles: AUST R 195919

Blisters: AUST R 195910

Available in bottles of 100 tablets and blisters of 1, 2, 3 and 15 tablets.

* Not all pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 500mg of azithromycin dihydrate as the active ingredient.

It also contains the following:

- calcium hydrogen phosphate dihydrate
- hydroxypropylcellulose
- croscarmellose sodium
- magnesium Stearate
- Opadry II 31K58875 White.

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

Sponsor

Arrotex Pharmaceuticals Pty Ltd
15 - 17 Chapel Street
Cremorne, Victoria 3121

This leaflet prepared in February 2023