

APO-AZITHROMYCIN

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 APO-AZITHROMYCIN?

APO-AZITHROMYCIN contains the active ingredient azithromycin dihydrate. APO-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. For more information, see Section [1. Why am I taking APO-AZITHROMYCIN?](#) in the full CMI.

2. What should I know before I take APO-AZITHROMYCIN?

Do not use if you have ever had an allergic reaction to APO-AZITHROMYCIN 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 take APO-AZITHROMYCIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-AZITHROMYCIN 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 APO-AZITHROMYCIN?

- 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.

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

5. What should I know while taking APO-AZITHROMYCIN?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are taking APO-AZITHROMYCIN.If you become pregnant while taking APO-AZITHROMYCIN, tell your doctor immediately.If your infection does not improve within a few days, or if your symptoms become worse, tell your doctor.If you get severe diarrhoea, tell your doctor immediately. Do this even if it occurs several weeks after you have stopped taking APO-AZITHROMYCIN.If you get a sore, white mouth or tongue while taking or soon after stopping APO-AZITHROMYCIN, tell your doctor. Also tell your doctor if you get vaginal itching or discharge.Protect your skin when you are in the sun, especially between 10am and 3pm.
Things you should not do	<ul style="list-style-type: none">Do not stop taking APO-AZITHROMYCIN, 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.
Driving or using machines	<ul style="list-style-type: none">This medicine is not expected to affect your ability to drive a car or operate machinery.
Looking after your medicine	<ul style="list-style-type: none">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.

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

6. Are there any side effects?

Tell your doctor if you notice any of the following and they worry you: dry mouth, altered sense of taste, nausea (feeling sick), vomiting, diarrhoea, constipation, blurred vision, difficulty in focusing, drowsiness, tiredness, headache, dizziness, lightheadedness, increased sweating, weight gain or loss and changes in sex drive. Tell your doctor immediately or go to the Emergency department at the nearest hospital if you notice any of the following: skin rash, itching, hives; swelling of the face or tongue; severe sunburn, blistering or swelling of the skin, fainting or collapse, chest pain and seizures or fits. 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.

APO-AZITHROMYCIN

Active ingredient: *azithromycin dihydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking APO-AZITHROMYCIN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking APO-AZITHROMYCIN.**

Where to find information in this leaflet:

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

1. Why am I taking APO-AZITHROMYCIN?

APO-AZITHROMYCIN contains the active ingredient azithromycin dihydrate. APO-AZITHROMYCIN is an antibiotic, which belongs to a group of medicines called azalides. The azalides are a sub-class of a group of antibiotics called macrolides.

APO-AZITHROMYCIN works by killing or stopping the growth of bacteria causing your infection.

APO-AZITHROMYCIN will not work against viral infections such as colds or flu.

APO-AZITHROMYCIN is used to treat infections in different parts of the body caused by bacteria.

It is commonly used to treat Chlamydia.

APO-AZITHROMYCIN is also used to prevent infections by a bacterium called Mycobacterium Avium- intracellulare Complex (MAC) in some people.

APO-AZITHROMYCIN is only available with a doctor's prescription.

APO-AZITHROMYCIN is not addictive.

2. What should I know before I take APO-AZITHROMYCIN?

Warnings

Do not take APO-AZITHROMYCIN if:

- you are allergic to azithromycin dihydrate, macrolide antibiotics (e.g. clarithromycin, erythromycin, roxithromycin, telithromycin) or any of the ingredients listed at the end of this leaflet.

- Always check the ingredients to make sure you can use this medicine.
- Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face/lips/tongue or to other parts of the body, skin rash, itching or hives.

Check with your doctor if you:

- have any other medical conditions:
 - any liver problems
 - any kidney problems
 - any heart problems, including heart rhythm abnormalities
 - diabetes, hereditary fructose intolerance, glucose-galactose malabsorption or saccharise-isomaltase deficiency
 - cystic fibrosis
 - muscle weakness
 - low levels of potassium or magnesium in your blood.
- are pregnant or if you plan to become pregnant or are breastfeeding. Your doctor can discuss with you the risks and benefits involved.
- take any medicines for any other condition.

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.

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 APO-AZITHROMYCIN and affect how it works.

- 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).
- 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.
- Diphenoxylate (Lomotil), 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 APO-AZITHROMYCIN or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

Talk to your doctor about the need for additional contraception while taking APO-AZITHROMYCIN.

Some antibiotics may decrease the effectiveness of some birth control pills, although this has not been shown with APO-AZITHROMYCIN.

4. How do I take APO-AZITHROMYCIN?

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.

When to take APO-AZITHROMYCIN

- APO-AZITHROMYCIN should be taken 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.

If you forget to take APO-AZITHROMYCIN

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 the dose you missed.

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 APO-AZITHROMYCIN

If you think that you have used too much APO-AZITHROMYCIN, 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.

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

5. What should I know while taking APO-AZITHROMYCIN?

Things you should do

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

If you are about to start any new medicines, tell your doctor and pharmacist that you are taking APO-AZITHROMYCIN.

Remind any doctor, dentist or pharmacist you visit that you are using APO-AZITHROMYCIN.

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.

Call your doctor straight away if:

- you get severe diarrhoea, tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after APO-AZITHROMYCIN 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 get a sore, white mouth or tongue while taking, or soon after stopping APO-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 APO-AZITHROMYCIN allows yeast to grow and the above symptoms to occur. APO-AZITHROMYCIN does not work against yeast.

- you become pregnant while taking APO-AZITHROMYCIN.
- during treatment with APO-AZITHROMYCIN your baby develops irritability with feeding or starts vomiting. This may be a sign of a stomach disorder in the infant.

Things you should not do

- Do not stop taking APO-AZITHROMYCIN 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 APO-AZITHROMYCIN to anyone else, even if they have the same condition as you.
- Do not use APO-AZITHROMYCIN to treat any other medical complaints unless your doctor tells you to.

Driving or using machines

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

Looking after your medicine

- 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.
- Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:
 - in the bathroom or near a sink, or
 - in the car or on window sills.

Heat and dampness can destroy some medicines.

- Keep this medicine where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

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
<ul style="list-style-type: none"> Oral thrush - white furry, sore tongue and mouth 	Speak to your doctor if you

Less serious side effects	What to do
<ul style="list-style-type: none"> 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. 	have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> Severe persistent diarrhoea (loose bowel motions). Fast or irregular heartbeat. 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. 	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.

Very serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none"> 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). 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very 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 APO-AZITHROMYCIN contains

Active ingredient (main ingredient)	Azithromycin dihydrate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• calcium hydrogen phosphate dihydrate• croscarmellose sodium• hypolose• magnesium stearate• Opadry II 31K58875 White (contains lactose monohydrate)
Potential allergens	Contains lactose

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

What APO-AZITHROMYCIN looks like

APO-AZITHROMYCIN is a white, oval, biconvex film coated tablet engraved "APO" on one side and "AZ500" on the other side.

Bottle: AUST R 195919, Blisters: AUSTR 195910

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

* Not all pack sizes may be available.

Who distributes APO-AZITHROMYCIN

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne, VIC 3121
Australia
www.arrotex.com.au

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