

# APO-AZITHROMYCIN TABLETS

Contains the active ingredient azithromycin (as azithromycin dihydrate)

## Consumer Medicine Information

### 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 taking Azithromycin 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 your medicine.**

You may need 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. It is commonly used to treat Chlamydia. Azithromycin is also used to prevent infections by a bacterium called Mycobacterium Aviumintracellulare Complex (MAC) in some people. 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.

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 azithromycin 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.

#### Use in children

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 azithromycin if you are allergic to:**

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

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 if the expiry date (EXP) printed on the packaging has passed 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 any other health problems, including:**

- any liver problems
- any heart problems, including abnormalities of the rhythm
- diabetes, hereditary fructose intolerance, glucose-galactose malabsorption or sacchariseisomaltase deficiency
- cystic fibrosis
- muscle weakness
- low levels of potassium or magnesium in your blood
- if you are pregnant or if you 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 them before you start taking azithromycin.**

#### Taking other medicines

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

Some medicines may interfere with Azithromycin or increase the risk of side effects. These include:

- antacids (medicines used to treat indigestion)
- coumarin-type oral anticoagulants (a medicine used to prevent blood clots)
- cyclosporin (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 Azithromycin 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 or pharmacist has more information on medicines to be careful with or to avoid while taking Azithromycin.

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

Some antibiotics may decrease the effectiveness of some birth control

pills, although this has not been shown with azithromycin.

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## How to take this medicine

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**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 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 is usually taken once a day. Sometimes the dose is taken once a week. Your doctor will decide the right dose for you.

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

### *How to take it*

Swallow the tablets whole with liquid. This medicine may be taken with or without food.

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 the same time each day. Taking it at the same time each day will have the best effect and 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 recommends. 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 to help you remember.

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## If you take too much (overdose)

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**Immediately telephone your doctor or Poisons Information Centre (telephone in Australia - 13 11 26; in New Zealand - 0800 POISONS or 0800 764 766) for advice if you think that you or anyone else may have taken too much Azithromycin.**

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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## While you are taking this medicine

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### *Things you must do*

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

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

**If you become pregnant while taking Azithromycin, tell your doctor.**

**Tell your doctor immediately if during treatment with Azithromycin your baby develops irritability with feeding or starts vomiting.**

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

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

**Tell any other doctors, dentists and pharmacists who are treating you that you are taking Azithromycin.**

### ***Things you must not do***

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

### ***Things to be careful of***

Be careful when 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.**

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## **Side effects**

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**Tell your doctor as soon as possible if you do not feel well while you are taking azithromycin or if you have any questions or concerns.**

Like other medicines, Azithromycin can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

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

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

### ***While taking it***

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

**See your doctor immediately 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
- 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
- dark urine or blood in the urine or bowel motions
- severe upper stomach pain, often with nausea and vomiting.

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

**If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident**

## **and Emergency department 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
- fainting
- convulsions (fits)

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

### ***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:

- 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. However, 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. 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.

**Do not be alarmed at this list of possible side effects.**

You may not experience any of them.

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## **Storage and disposal**

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### ***Storage***

Keep your medicine in its original packaging until it is time to take it.

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

Keep your medicine in a cool dry place where the temperature will stay 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 it has passed its expiry date, ask your pharmacist what to do with any that is left over.**

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## **Product description**

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### ***What it looks like***

Apo-Azithromycin come in two strengths:

- Apo-Azithromycin 250mg tablets are white, oval, film-coated tablets. Embossed

“AZ250” on one side, and “APO” on the other.

- Apo-Azithromycin 500mg tablets are white, oval, film-coated tablet Embossed “AZ500” on one side, and “APO” on the other.

Available in blister of 2 tablets and bottles of 30 and 500 tablets.

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

### ***Ingredients***

#### ***Active Ingredient:***

Each capsule contains either 250 mg or 500 mg of azithromycin (as dihydrate).

They also contain the following inactive ingredients:

- calcium hydrogen phosphate dihydrate
- hydroxypropyl cellulose
- croscarmellose sodium
- magnesium stearate (intragranular)
- magnesium stearate (extragranular)
- opadry II 31K58875 white

Apo-Azithromycin tablets do not contain lactose, sucrose, gluten or tartrazine.

### ***Sponsor***

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