

## APO-Azithromycin Tablets

Contains the active ingredient azithromycin (as azithromycin dihydrate)

### Consumer Medicine Information

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

#### What is in this leaflet

##### Read this leaflet carefully before taking your medicine.

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.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

##### Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from [www.apotex.com.au](http://www.apotex.com.au).

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

#### What this medicine is used for

The name of your medicine is APO-Azithromycin. It contains the active ingredient azithromycin (as azithromycin dihydrate).

It is used to treat infections in different parts of the body caused by bacteria. It is commonly used to treat chlamydia.

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.

##### How it works

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.

There is no evidence that this medicine is addictive.

##### 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

**You are hypersensitive to, or have had an allergic reaction to, azithromycin, any other macrolide or ketolide antibiotic (e.g. clarithromycin, erythromycin, roxithromycin, telithromycin) or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include cough, 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;

**If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**

- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.

##### Before you start to take it

**Before you start taking this medicine, tell your doctor if:**

1. You have allergies to:
  - any other medicines
  - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
  - liver problems
  - severe kidney problems
  - heart problems, including heart rhythm abnormalities
  - electrolyte disturbance, particularly low levels of potassium or magnesium in your blood
3. You have pneumonia and the following risk factors: cystic fibrosis, infection occurring in hospital, infection of the blood, hospital admission, are elderly or have significant health problems (including immunodeficiency).
4. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
5. You are currently breast-feeding or you plan to breast-feed. Do not take this medicine whilst breast-feeding until you and your doctor have discussed the risks and benefits involved.
6. You are planning to have surgery or an anaesthetic.
7. You are currently receiving or are planning to receive dental treatment.
8. You are taking or are planning to take any other medicines; this includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with azithromycin. These include:

- antacids (medicines used to treat indigestion)
- coumarin-type oral anti-coagulants (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 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
- 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. If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with azithromycin.

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

#### How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

##### How much to take

Your doctor will tell you how much of this medicine you should take. This will depend 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.

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.

### ***If you take too much (overdose)***

**If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.**

**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**

#### ***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.

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Go to your doctor regularly for a check-up.

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

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

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to.
- Stop taking your medicine, or change the dosage, without first 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.

### ***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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### **Possible side effects**

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.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

#### **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.

#### **Tell your doctor as soon as possible and before you take your next dose of azithromycin if you notice any of the following.**

These may be serious side effects and you may need urgent medical attention:

- 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.

#### **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.**

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

- 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).

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.

### ***Allergic reactions***

If you think you are having an allergic reaction to azithromycin, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, 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
- fainting
- hay fever-like symptoms.

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### **Storage and disposal**

#### ***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 or pharmacist tells you to stop taking this medicine or they have passed their expiry date, your pharmacist can dispose of the remaining medicine safely.

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### **Product description**

#### ***What APO-Azithromycin looks like***

Azithromycin 500mg tablets are white, oval, biconvex film coated tablets engraved "APO" on one side and "AZ500" on the other side.

It is 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 (as azithromycin dihydrate) as the active ingredient.

It also contains the following inactive ingredients:

- Calcium hydrogen phosphate
- Hydroxypropylcellulose
- Croscarmellose sodium
- Magnesium Stearate
- Opadry II 31K58875 White.

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes. This medicine contains lactose.

***Australian Registration Numbers***

APO-Azithromycin 500mg tablets Bottles: AUST R 195919

Blisters: AUST R 195910

***Sponsor***

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Australia

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