

AZITHROMYCIN MYLAN

azithromycin (as dihydrate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about AZITHROMYCIN MYLAN.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking AZITHROMYCIN MYLAN against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What AZITHROMYCIN MYLAN 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.

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

It contains the active ingredient azithromycin.

AZITHROMYCIN MYLAN 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 MYLAN 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.

AZITHROMYCIN MYLAN is only available with a doctor's prescription.

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 MYLAN

When you must not take it

You must not take AZITHROMYCIN MYLAN if you have an allergy to:

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

If you are not sure if you are allergic to any of the above, ask your doctor.

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

- Skin rash, itching or hives.

You must not take AZITHROMYCIN MYLAN after the expiry date (EXP) or use by date printed on the pack 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 be given 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 kidney problems
- any liver problems
- any heart problems including abnormalities of the rhythm
- diabetes, hereditary fructose intolerance, glucose-galactose malabsorption or saccharase-isomaltase deficiency
- cystic fibrosis
- myasthenia gravis; 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 him/her before you are given AZITHROMYCIN MYLAN.

Taking other medicines

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

Some medicines may interfere with AZITHROMYCIN MYLAN. These include:

- antacids (a medicine used to treat indigestion)
- colchicine (a medicine used to treat gout)
- coumarin-type oral anticoagulants (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 heart failure)
- ergot derivatives (such as ergotamine, a medicine used to treat migraines)
- terfenadine or astemizole (medicines used to treat allergies and hayfever)
- 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 MYLAN, 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 avoid while taking AZITHROMYCIN MYLAN.

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

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

How to take AZITHROMYCIN MYLAN

Follow all directions given to you by your doctor and 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

Your doctor will decide how much AZITHROMYCIN MYLAN you should receive and the length of time for which you should receive it.

The dose will depend on your infection.

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

For other infections AZITHROMYCIN MYLAN 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.

How to take it

Swallow the tablets whole with a full glass of water.

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



When to take AZITHROMYCIN MYLAN

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 MYLAN.

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

How long to take AZITHROMYCIN MYLAN

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 forget to take it

If you are taking AZITHROMYCIN MYLAN 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 too much is given (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 MYLAN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

While you are taking AZITHROMYCIN MYLAN

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 AZITHROMYCIN MYLAN 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 MYLAN. 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 MYLAN does not work against yeast.

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

If you are about to be started on any new medicine, remind your doctor and

pharmacist that you are taking AZITHROMYCIN MYLAN.

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

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

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

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.

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 MYLAN 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.

Side effects

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

Like other medicines, AZITHROMYCIN MYLAN 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, 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 side effects are usually mild.

Tell your doctor immediately and before you take the next dose 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.

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

If any of the following happen, stop taking AZITHROMYCIN MYLAN and 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
- 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 MYLAN:

- severe stomach cramps
- watery and severe diarrhoea, which may be bloody
- fever, in combination with one or both of the above

AZITHROMYCIN MYLAN 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.

After taking AZITHROMYCIN MYLAN

Storage

Keep your medicine in the original container until it's time to take them.

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 MYLAN 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 MYLAN comes in one type of tablet:

AZITHROMYCIN MYLAN 500mg - white to off-white, film-coated, oval shaped 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.

Active Ingredient

AZITHROMYCIN MYLAN contains 500mg of azithromycin (as azithromycin dihydrate).

Other Ingredients

It also contains the following inactive ingredients:

- microcrystalline cellulose
- maize starch
- sodium starch glycollate
- colloidal anhydrous silica
- magnesium stearate
- sodium lauryl sulfate
- lactose monohydrate
- hypromellose
- titanium dioxide
- macrogol 4000

AZITHROMYCIN MYLAN contains lactose and sulfites.

Supplier

Alphapharm Pty Ltd trading as Viatris
Level 1, 30 The Bond

30-34 Hickson Road
Millers Point NSW 2000
www.viatris.com.au
Phone: 1800 274 276

Australian registration numbers:

AZITHROMYCIN MYLAN 500 mg film coated tablet: AUST R 158290 (blisters).

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