Azithromycin Mylan
contains the active ingredient azithromycin

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 subclass 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.

This medicine is not addictive

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, or any other ketolide or macrolide antibiotics (e.g. roxithromycin, erythromycin, clarithromycin, telithromycin) or 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 if the expiry date (EXP) or use by date printed on the pack has passed. If you take this medicine after this date, it may not work.

Azithromycin Mylan must not be taken if the packaging is torn or shows signs of tampering. 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
- any fungal infections
- any allergies, especially to other antibiotics
- any medical conditions that affect your immune system
- any heart, liver or kidney problems
- any lupus
- any blood disorders
- any diabetes
- any thyroid problems
- any high cholesterol or triglyceride levels
- any lung or breathing problems
- any cancer
- any depression
- any peptic ulcer or stomach bleeding
- any psychiatric disorder
- any drug or alcohol abuse
- any seizures or nervous system disorders
- any problems with the immune system
- any organ transplant rejection or to treat certain infections
- any condition that might affect levels of vitamin D in the body

Tell your doctor if you are taking any other medicines to be careful with or avoid while taking Azithromycin Mylan.

Some medicines may interfere with Azithromycin Mylan. These include:

- antacids (a medicine 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 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)
- medicines used to treat diarrhoea such as Lomotil®.

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.

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.

If you take the wrong dose, Azithromycin Mylan may not work as well and your problem may not improve.

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 Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) 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 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 Azithromycin Mylan.

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

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

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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.

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 infection that is making you feel unwell.

Do not take Azithromycin Mylan if you do not complete the full course prescribed by your doctor.

Tell your doctor if you do not feel well while you are taking Azithromycin Mylan.

These 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
- 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 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
- aggressive reaction, nervousness, agitation or anxiety
- bleeding or bruising more easily than normal, reddish or purple 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 that may require medical attention. Serious side effects are rare.

Product description

What it looks like

Azithromycin Mylan comes in one type of tablet: Azithromycin Mylan 500mg - white to off-white, oval, film-coated 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 dihydrate).

Other Ingredients

It also contains the following inactive ingredients:

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

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

Supplier

Azithromycin Mylan is supplied in Australia by:

Alphapharm Pty Limited
(ABN 93 002 359 739)
Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
Phone: (02) 9298 3999
www.mylan.com.au
Australian registration numbers:
Azithromycin Mylan 500 mg film coated tablet: AUST R 158290 (blisters).
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