

AZITHROMYCIN VIATRIS

Azithromycin dihydrate (a-zithro-my-sin)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about AZITHROMYCIN VIATRIS. 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 VIATRIS 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 the medicine.

You may need to read it again.

What AZITHROMYCIN VIATRIS is used for

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

It is commonly used to treat Chlamydia. AZITHROMYCIN VIATRIS is also used to prevent infections by a bacterium called *Mycobacterium Avium-intracellulare Complex (MAC)* in some people.

AZITHROMYCIN VIATRIS 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 VIATRIS works by killing or stopping the

growth of bacteria causing your infection.

AZITHROMYCIN VIATRIS 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 VIATRIS 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 VIATRIS

When you must not take it

Do not take AZITHROMYCIN VIATRIS if you have an allergy 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.

Some of the 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 or have had any of the following medical conditions:

- any liver problems
- any kidney problems
- any heart problems, including abnormalities of the rhythm
- diabetes, hereditary fructose intolerance, glucose-galactose malabsorption or saccharise-isomaltase deficiency
- cystic fibrosis
- muscle weakness
- low levels of potassium or magnesium in your blood

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

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 VIATRIS.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you

get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and AZITHROMYCIN VIATRIS may interfere with each other or increase the risk of side effects. These include:

- 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 AZITHROMYCIN VIATRIS 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 and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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

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

How to take AZITHROMYCIN VIATRIS

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

Your pharmacist will explain how to use it if you are not sure.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

AZITHROMYCIN VIATRIS may be taken with or without food.

If you need to take an antacid (e.g. Gastrogel, Mylanta), take it at least 1 hour before or 2 hours after your dose of AZITHROMYCIN VIATRIS dose.

This will avoid any possible effect of the antacid on the absorption of AZITHROMYCIN VIATRIS.

How long to take it

Continue taking AZITHROMYCIN VIATRIS until you finish the pack or until your doctor recommends.

Do not stop taking it because you feel better.

If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.

If you are not sure how long you should be taking AZITHROMYCIN VIATRIS, check with your doctor.

If you forget to take it

If you are taking AZITHROMYCIN VIATRIS 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 try to make up for missed doses by taking more than one dose at a time.

If you are not sure what to do, check with your doctor or pharmacist.

If you have trouble remembering to take your AZITHROMYCIN VIATRIS, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the 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 may have taken too much AZITHROMYCIN VIATRIS. Do

this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

While you are using AZITHROMYCIN VIATRIS

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 have chest pain, shortness of breath, sudden dizziness, light-headedness or numbness in the face, arm, or leg, tell your doctor, pharmacist or nurse immediately. You may need urgent medical attention.

If you get severe diarrhoea, tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after AZITHROMYCIN VIATRIS 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.

If you get a sore, white mouth or tongue while taking, or soon after stopping AZITHROMYCIN VIATRIS, 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 VIATRIS allows yeast to grow and the above symptoms to occur.

AZITHROMYCIN VIATRIS does not work against yeast.

If you become pregnant while taking AZITHROMYCIN VIATRIS, tell your doctor.

Tell your doctor immediately if during treatment with

AZITHROMYCIN VIATRIS 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 VIATRIS.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking AZITHROMYCIN VIATRIS.

Things you must not do

Do not stop taking AZITHROMYCIN VIATRIS 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 VIATRIS to anyone else, even if they have the same condition as you.

Do not use AZITHROMYCIN VIATRIS to treat any other medical complaints unless your doctor tells you to.

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.

Side effects

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

Like other medicines, AZITHROMYCIN VIATRIS 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
- rash
- hearing loss or ringing in the ears
- altered taste and smell.

These side effects are usually mild.

See your doctor immediately and before you take your next dose of AZITHROMYCIN VIATRIS 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 any of the following happen, stop taking AZITHROMYCIN VIATRIS 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
- shortness of breath
- pain or discomfort in the jaw, neck, back, arm, or shoulder
- sudden dizziness or lightheadedness
- cold sweat
- numbness or weakness in the face, arm, or leg
- trouble speaking or understanding what others are saying

- problems with vision
- trouble walking, loss of balance, or lack of coordination
- 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 VIATRIS:

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

AZITHROMYCIN VIATRIS 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 using AZITHROMYCIN VIATRIS

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store AZITHROMYCIN VIATRIS 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 VIATRIS tablets come in one strength:

- AZITHROMYCIN VIATRIS 500 mg - white, film-coated tablets scored on one side. Blister packs of 2 and 3.

Ingredients

AZITHROMYCIN VIATRIS contains 500 mg of azithromycin dihydrate as the active ingredient.

Other ingredients include:

- Pregelatinised maize starch
- Crospovidone
- calcium hydrogen phosphate

- magnesium stearate
- sodium lauryl sulfate
- lactose monohydrate
- hypromellose
- titanium dioxide
- triacetin

Supplier

Sponsor

Helix Pharmaceuticals Pty Ltd
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