

AZITHROMYCIN VIATRIS

azithromycin (as monohydrate)

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 benefits and risks. Your doctor has weighed the risks of you being given AZITHROMYCIN VIATRIS against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What AZITHROMYCIN VIATRIS is used for

AZITHROMYCIN VIATRIS is used to treat pneumonia, a lung infection caused by certain bacteria including *Legionella pneumophila*.

This medicine 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.

This medicine 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 AZITHROMYCIN VIATRIS has been prescribed for you. Your doctor may have prescribed AZITHROMYCIN VIATRIS for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Before you are given AZITHROMYCIN VIATRIS

When you must not be given it

You must not be given AZITHROMYCIN VIATRIS if you have an allergy to:

Azithromycin or any other ketolide or macrolide antibiotic (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.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

The safety and effectiveness of this medicine in children has not been established.

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
- muscle weakness
- inflammation of the large bowel
- a fungal infection
- low levels of potassium or magnesium in your blood
- myasthenia gravis

Tell your doctor if you are pregnant or if you plan to become pregnant or are breastfeeding or plan to breastfeed.

Your doctor will discuss the possible risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you are given AZITHROMYCIN VIATRIS.

AZITHROMYCIN VIATRIS must not be given if the expiry date (EXP) printed on the pack has passed or if the packaging is torn or shows signs of tampering. If you take this medicine after this date, it may not work.

If you are not sure whether you should be given this medicine, talk to your doctor.

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 VIATRIS. These include:

- antacids (a medicine used to treat indigestion or heartburn)
- colchicine (a medicine used to treat gout)
- coumarin-type oral anticoagulants (a medicine used to prevent blood clots, such as warfarin)
- 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 e.g. atrial fibrillation)
- ergot derivatives (a medicine used to treat migraines, such as ergotamine)
- terfenadine or astemizole (medicines used to treat allergies and hayfever)
- zidovudine (a medicine used to treat patients with AIDS)
- 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 or pharmacist has more information on medicines to be careful with or avoid while being given AZITHROMYCIN VIATRIS.

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

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

How AZITHROMYCIN VIATRIS is given

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

How much is given

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

The usual dose of AZITHROMYCIN VIATRIS is 500 mg given as an injection into a vein for 2 to 5 days.

Following this, you may be given oral Azithromycin daily for another 2-7 days, to complete a 7 to 10 day course of antibiotics.

This treatment may be followed by a course of oral antibiotics.

How it is given

AZITHROMYCIN VIATRIS is given as an injection by a doctor or trained nurse.

AZITHROMYCIN VIATRIS is a powder which is mixed with Water for Injections and then diluted by the

pharmacist. It is then injected into a vein which takes approximately 60 minutes.

If too much is given (overdose)

As AZITHROMYCIN VIATRIS is given under the close supervision of your doctor, it is very unlikely that you will receive too much. If you experience any side effects tell your doctor immediately.

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

You may need urgent medical attention.

While you are being treated

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.

Tell your doctor, pharmacist or nurse immediately if you get severe diarrhoea. 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.

Tell your doctor if you get a sore, white mouth or tongue while being given, or soon after stopping AZITHROMYCIN VIATRIS. 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 being given this medicine, 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.

Tell all other doctors, dentists and pharmacists who are treating you that you are being given AZITHROMYCIN VIATRIS, especially if you are being started on any new medicines.

Things to be careful of

Protect your skin when you are in the sun, especially between 10am and 3pm. If outdoors, wear protective clothing and use a 30+ sunscreen. If your skin does appear to be burning tell your doctor immediately.

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.

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.

Side effects

Tell your doctor, nurse 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 maybe 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:

- pain or inflammation at the site of infusion and pain during infusion
- 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, loose bowel motions
- headache, spinning sensation
- tiredness, drowsiness, fatigue
- muscle or joint aches

- hearing loss or ringing in the ears
- altered taste and smell.

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- severe persistent diarrhoea
- 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 and swollen lymph nodes
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- dark urine or blood in the urine or bowel motions
- aggressive reaction, nervousness, agitation or anxiety
- severe upper stomach pain, often with nausea and vomiting.

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

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
- pain or discomfort in the jaw, neck, back, arm or shoulder
- sudden dizziness or light-headedness
- 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

AZITHROMYCIN VIATRIS is stored in the pharmacy or on the ward. It is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

Disposal

The hospital staff will dispose of any left-over AZITHROMYCIN VIATRIS.

Product description

What it looks like

AZITHROMYCIN VIATRIS is a white to off-white lyophilized powder, or cake presented in a 10 mL glass vial.

AZITHROMYCIN VIATRIS contains 500 mg of azithromycin powder for solution for infusion, providing 100 mg/mL solution following reconstitution.

Active Ingredient

The active ingredient is azithromycin.

Other Ingredients

It also contains the following inactive ingredients:

- citric acid monohydrate
- sodium hydroxide

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

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