

AZITHROMYCIN VIATRIS

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being treated with AZITHROMYCIN VIATRIS?

AZITHROMYCIN VIATRIS contains the active ingredient azithromycin. It is used to treat pneumonia, a lung infection caused by certain bacteria.

For more information, see Section [1. Why am I being treated with AZITHROMYCIN VIATRIS?](#) in the full CMI.

2. What should I know before treatment with AZITHROMYCIN VIATRIS?

You should not be given AZITHROMYCIN VIATRIS if you have ever had an allergic reaction to azithromycin or any other ketolide or macrolide antibiotic (e.g. roxithromycin, erythromycin, clarithromycin, telithromycin), or citric acid.

Tell your doctor if you have kidney, liver or heart problems including abnormalities of the rhythm; muscle weakness; low levels of potassium or magnesium in your blood; take any other medicines; are pregnant or plan to become pregnant, or are breastfeeding.

For more information, see Section [2. What should I know before treatment with AZITHROMYCIN VIATRIS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with AZITHROMYCIN VIATRIS and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is AZITHROMYCIN VIATRIS given?

AZITHROMYCIN VIATRIS is given as a slow infusion “drip” into a vein by a doctor or trained nurse.

More instructions can be found in Section [4. How is AZITHROMYCIN VIATRIS given?](#) in the full CMI.

5. What should I know during treatment of AZITHROMYCIN VIATRIS?

Things you should do	
	• Talk to your doctor if the symptoms of your

	infection do not improve within a few days or they become worse. • Talk to your doctor about the need for additional method of contraception; if you become pregnant; if you breastfeed or your baby develops irritability with feeding or starts vomiting. • Tell all doctors, dentists or pharmacists who are treating you that you are being given AZITHROMYCIN VIATRIS.
Things you should not do	• Do not breastfeed your baby without discussing the risks with your doctor.
Driving or using machines	• This medicine is not expected to affect your ability to drive a car or operate machinery.
Looking after your medicine	• AZITHROMYCIN VIATRIS is stored in the pharmacy or on the

	hospital ward under the correct conditions.
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For more information, see Section [5. What should I know during treatment of AZITHROMYCIN VIATRIS?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects include pain at injection site; oral/vaginal thrush; nausea; vomiting; loss of appetite; altered taste/smell; abnormal hearing; muscle pain; stomach pain; constipation; indigestion; dizziness; headache; spinning sensation; drowsiness; fatigue; restlessness. **Serious side effects include** diarrhoea; aggression; nervousness; agitation; anxiety; chest pain; palpitations; sweat; shortness of breath; wheezing; convulsions; fainting; rash, itching or hives; swelling of face, lips, tongue or body; sunburn; decreased sensitivity especially skin; blisters or ulcers on skin, mouth or airways; fever; numbness or weakness; trouble speaking, understanding or walking; loss of balance; lack of coordination; altered vision; dark urine or blood in urine or bowel motions; jaundice. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

AZITHROMYCIN VIATRIS

Active ingredient: *azithromycin (as monohydrate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using AZITHROMYCIN VIATRIS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using AZITHROMYCIN VIATRIS.**

Where to find information in this leaflet:

- [1. Why am I being treated with AZITHROMYCIN VIATRIS?](#)
- [2. What should I know before treatment with AZITHROMYCIN VIATRIS?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is AZITHROMYCIN VIATRIS given?](#)
- [5. What should I know during treatment with AZITHROMYCIN VIATRIS?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being treated with AZITHROMYCIN VIATRIS?

AZITHROMYCIN VIATRIS contains the active ingredient azithromycin (as monohydrate).

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.

AZITHROMYCIN VIATRIS is used to treat pneumonia, a lung infection caused by certain bacteria. It 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.

Your doctor may have prescribed AZITHROMYCIN VIATRIS for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

There is no evidence that AZITHROMYCIN VIATRIS is addictive.

2. What should I know before treatment with AZITHROMYCIN VIATRIS?

Warnings

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

- azithromycin, any other ketolide or macrolide antibiotic (e.g., roxithromycin, erythromycin, clarithromycin, telithromycin) or citric acid
- 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.

Some of the symptoms of an allergic reaction may include:

- skin rash, itching or hives ,
- swelling of the face, lips, tongue or other parts of the body
- shortness of breath, wheezing or difficulty breathing.

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

Check with your doctor if you have ever had the following medical conditions:

- kidney problems
- liver problems
- heart problems, including abnormalities of the rhythm
- muscle weakness
- low levels of potassium or magnesium in your blood

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Talk your doctor if you are pregnant or plan to become pregnant.

Talk your doctor if you are breastfeeding or plan to breastfeed.

Your doctor will discuss with you the risks and benefits involved.

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

Use in children

The safety and effectiveness of AZITHROMYCIN VIATRIS in children have not been established.

3. What if I am taking other medicines?

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

Some medicines may interfere with AZITHROMYCIN VIATRIS and affect how it works. 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
- atorvastatin, a medicine used to lower cholesterol

- 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 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.

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

Your doctor or pharmacist has more information on medicines to be careful with or avoid while being given AZITHROMYCIN VIATRIS.

4. How is AZITHROMYCIN VIATRIS given?

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 for 2 to 5 days.

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

How is AZITHROMYCIN VIATRIS given

AZITHROMYCIN VIATRIS is given through slow infusion “drip” into a vein by your doctor or nurse over a period about 60 minutes.

If you are given too much AZITHROMYCIN VIATRIS

As AZITHROMYCIN VIATRIS will most likely be given to you in hospital under the supervision of your doctor, it is very unlikely that you will receive too much.

However, if you experience any side effects, especially abnormal hearing, tell your doctor or nurse immediately. If you are not already in hospital, go to Accident and Emergency at the nearest hospital or immediately contact the Poisons

Information Centre for advice on overdose (Call 13 11 26).

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

5. What should I know during treatment with AZITHROMYCIN VIATRIS?

Things you should do

Tell any doctor, nurse or pharmacist if:

- **the symptoms of your infection do not improve within a few days, or if they become worse**
- **you have chest pain, shortness of breath, sudden dizziness, light-headedness or numbness in the face, arm, or leg**
- **you get severe diarrhoea, even if it happens several weeks after treatment with AZITHROMYCIN VIATRIS has been stopped.**

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care.

- **you get a sore, white mouth or tongue while being given, or soon after stopping AZITHROMYCIN VIATRIS or you get vaginal itching or discharge.**

These symptoms 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.

- **you become pregnant while being given AZITHROMYCIN VIATRIS**
- **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.

- **you are about to start any new medicines.**

If you are about to start any new medicines, tell your doctor and pharmacist that you are being given AZITHROMYCIN VIATRIS.

Tell all doctors, dentists and pharmacists who are treating you that you are being given AZITHROMYCIN VIATRIS.

Things to be careful of

Protect your skin when you are in the sun, especially between 10 am and 3 pm. If outdoors, wear protective clothing and use a 30+ sunscreen.

AZITHROMYCIN VIATRIS may cause your skin to be much more sensitive to sunlight than it is normally. Exposure to sunlight may cause a skin rash, itching, redness, or severe sunburn.

If your skin does appear to be burning tell your doctor immediately.

Things you must not do

- **Do not stop having treatment with AZITHROMYCIN VIATRIS 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 any other medicines whether they require a prescription or not without first telling your doctor or consulting with a pharmacist.

Driving or using machines

Be careful driving or operating machinery until you know how AZITHROMYCIN VIATRIS affects you.

Whilst it is unlikely that you will drive or operate machinery when having AZITHROMYCIN VIATRIS, you need to be aware that AZITHROMYCIN VIATRIS may cause side effects such as dizziness. This may affect your ability to drive or operate machinery.

Drinking alcohol

No information is available.

Looking after your medicine

AZITHROMYCIN VIATRIS is stored in the pharmacy or on the hospital ward under the correct conditions.

Disposal of AZITHROMYCIN VIATRIS

The hospital staff will dispose of any leftover AZITHROMYCIN VIATRIS.

6. Are there any side effects?

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being treated with AZITHROMYCIN VIATRIS.

AZITHROMYCIN VIATRIS is effective against certain serious infections for most people but it may have unwanted side effects in some.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• pain or inflammation at injection site • oral thrush - white, furry, sore tongue and mouth	Speak to your nurse or doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
• vaginal thrush - sore and itchy vagina and/or white discharge • nausea (feeling sick) • vomiting, loss of appetite • constipation • stomach pain, indigestion, wind • dizziness, spinning sensation • headache • tiredness, drowsiness, fatigue, restlessness • muscle or joint aches • rash • hearing loss or ringing in the ears • altered taste and smell.	

Serious side effects

Serious side effects	What to do
• diarrhoea (usually with	Alert your nurse

Serious side effects	What to do
bloo and muc stom pain and feve • severe uppe stom pain after with naus and vom • fast or irreg hear palp • ches pain • sudd dizzi or light	or doctor straight away if you notice any of these serious side effects. ness

Serious side effects	What to do
• cold sweats • sudden signs of allergic reaction such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of	

Serious side effects	What to do
breathlessness when lying down or trouble breathing • widespread body rash, fever and swollen lymph nodes • symptoms of sunburn such as redness, itching, swelling or blisters which may occur more quickly	

Serious side effects	What to do
than normal • decreased feeling or sensation especially in the skin • signs of frequent or worried infection such as fever, severe chills, sore throat or mouth ulcers • bleeding or	

Serious side effects	What to do
bruise more easily than normal, redness or purple blotches under the skin • dark urine or blood in the urine or bowel motion • blisters or ulcers on the skin in	

Serious side effects	What to do
the mouth or airway that may occur after a period of fever, yellowing of the eyes or skin, also called jaundice. • pain or discomfort in the jaw, neck, back	

Serious side effects	What to do
arm, leg or shoulder • numbness or weakness in the face, arm, or leg • trouble with speech or understanding what others are saying • aggressive reactions, nervousness, agitation or anxiety	

Serious side effects	What to do
• prob with visio • trou walk loss of of bala or lack of coord • faint • conv (fits)	

The above list includes very serious side effects. You may

need urgent medical attention or hospitalisation.

Tell your doctor, nurse or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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 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 abdominal or 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.

Do not take any medicine for this diarrhoea without first checking with your doctor.

Ask your doctor, nurse or pharmacist if you don't understand anything in these lists.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What AZITHROMYCIN VIATRIS contains

Active ingredient (main ingredient)	azithromycin
Other ingredients (inactive ingredients)	• citric acid monohydrate • sodium hydroxide

Do not take this medicine if you are allergic to any of these ingredients.

What AZITHROMYCIN VIATRIS 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 (AUST R 191947).

Who distributes AZITHROMYCIN VIATRIS

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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