

Azithromycin Alphapharm

azithromycin (as monohydrate)

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about AZITHROMYCIN ALPHAPHARM.

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 ALPHAPHARM 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 ALPHAPHARM is used for

AZITHROMYCIN ALPHAPHARM 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 ALPHAPHARM will not work against viral infections such as colds or flu.

Ask your doctor if you have any questions about why AZITHROMYCIN ALPHAPHARM has been prescribed for you. Your doctor may have prescribed AZITHROMYCIN ALPHAPHARM 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 ALPHAPHARM

When you must not be given it

You must not be given AZITHROMYCIN ALPHAPHARM 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.

Before you are given 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
- 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. 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 ALPHAPHARM.

AZITHROMYCIN ALPHAPHARM must not be given 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 ALPHAPHARM must not be given 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.

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 ALPHAPHARM. These include:

- ergot derivatives (such as ergotamine, a medicine used to treat migraines)
- antacids (a medicine used to treat indigestion or heartburn)
- 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)
- 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 ALPHAPHARM 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 ALPHAPHARM.

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

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

How AZITHROMYCIN ALPHAPHARM 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 ALPHAPHARM you should receive and the length of time for which you should receive it.

The usual dose of AZITHROMYCIN ALPHAPHARM 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 ALPHAPHARM is given as an injection by a doctor or trained nurse.

AZITHROMYCIN ALPHAPHARM 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.

It may be given with or without food.

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

If too much is given (overdose)

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

ALPHAPHARM, 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 ALPHAPHARM allows yeast to grow and the above symptoms to occur. AZITHROMYCIN ALPHAPHARM does not work against yeast.

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

If you are about to start any new medicines, tell your doctor and pharmacist that you are taking AZITHROMYCIN ALPHAPHARM.

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

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 AZITHROMYCIN ALPHAPHARM 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 ALPHAPHARM to anyone else, even if they have the same condition as you.

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

Side effects

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

Like other medicines, AZITHROMYCIN ALPHAPHARM 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
- 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.

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
- 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 ALPHAPHARM 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 ALPHAPHARM:

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

AZITHROMYCIN ALPHAPHARM 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 ALPHAPHARM

Storage

AZITHROMYCIN ALPHAPHARM is stored in the pharmacy or on the

ward. It is kept in a cool dry place where the temperature stays below 25°C.

Disposal

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

Product description

What it looks like

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

AZITHROMYCIN ALPHAPHARM 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

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

Supplier

Alphapharm Pty Limited

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers:

AZITHROMYCIN ALPHAPHARM
500 mg Powder for Injection:

AUST R 191947

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