

AZITH

azithromycin (as monohydrate)

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about AZITH.

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 AZITH 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 AZITH is used for

AZITH is an antibiotic which contains azithromycin as the active ingredient. Azithromycin belongs to a group of medicines called azalides which are a sub-class of a group of antibiotics called macrolides.

AZITH is used to treat pneumonia, a lung infection caused by certain bacteria such as Legionella pneumophila.

AZITH works by killing or stopping the growth of bacteria causing the infection.

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

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

Your doctor may have prescribed it for another purpose.

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

There is no evidence that it is addictive.

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

Before you are given it

When you must not be given it

You must not be given AZITH if you have ever had an allergic reaction to:

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

- any of the ingredients listed at the end of this leaflet.

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.

AZITH must not be given to children.

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

AZITH must not be given if the expiry date printed on the pack 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 be given AZITH, talk to your doctor.

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 are pregnant or plan to become pregnant.

Your doctor will discuss the possible risks and benefits of taking this medicine during pregnancy.

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

Your doctor will discuss the possible risks and benefits of during breast-feeding.

Tell your doctor if you have or have had any of the following medical conditions:

- diabetes mellitus (sugar diabetes)
- kidney problems
- liver problems
- heart problems
- myasthenia gravis

If you have not told your doctor about any of the above, tell them before you start being given AZITH.

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 AZITH. 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 in transplant patients
- digoxin, a medicine used to treat abnormal heart rhythm e.g. atrial fibrillation
- 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 AZITH 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 having this medicine.

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

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

How it is given

AZITH is a sterile powder which is dissolved in sterile water for injections and then diluted before use. It is given as a slow injection into a vein, known as a continuous infusion or a 'drip'.

It will take at least 60 minutes for the solution containing your dose of AZITH to be infused into your vein.

Your doctor or nurse will prepare the infusion for you.

How much to be given

Your doctor will decide the dose of

AZITH you will be given by infusion and for how long.

You may then be given oral azithromycin to take in order to complete a 7 to 10 day course of antibiotic therapy.

Things to be aware of

If you are given too much (overdose)

As AZITH is given under the close supervision of your doctor, it is unlikely that you will receive too much.

However, if you experience any side effects after being given AZITH, tell your doctor immediately.

While you are using it

Things you must do

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

Tell your doctor, pharmacist or nurse immediately if you get severe diarrhoea. Do this even if it occurs several weeks after AZITH 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 AZITH.

Tell your doctor if you get vaginal itching or discharge.

This may mean you have a yeast infection called thrush. Sometimes the use of AZITH allows yeast to grow and the

above symptoms to occur. AZITH does not work against yeast.

Tell your doctor if you become pregnant while taking AZITH.

Tell all other doctors, dentists and pharmacists who are treating you that you are taking AZITH, 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 10 am and 3 pm. 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 like AZITH may cause 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 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 give your medicine to anyone else even if they have the same condition as you.

Do not use your medicine 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 having AZITH.

Like other medicines, AZITH 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 to answer any questions you may have.

Tell your doctor if you notice any of the following side effects and they worry you:

- pain 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
- rash
- dizziness, headache, spinning sensation

- tiredness, drowsiness, fatigue
- muscle or joint aches
- hearing loss or ringing in the ears
- altered taste and smell
- inability to feel or touch as normal.

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

- aggressive reaction, nervousness and anxiety
- severe persistent diarrhoea
- fast or irregular heartbeat, chest pain
- jaundice, yellowing of the skin and eyes
- fainting
- difficulty breathing
- swelling of the face, lips or tongue
- hives, itching or skin rash
- symptoms of sunburn such as redness, itching, swelling or blistering which may occur more quickly than normal
- severe blistering or peeling of the skin

- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal
- blood in the urine or bowel motions
- little or no urine
- convulsions (fits)
- severe upper stomach pain, often with nausea and vomiting.

The above list includes serious side effects which may require medical attention. 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 AZITH:

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

AZITH 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. 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 people.

Do not be alarmed by this list of side effects.

You may not experience any of them.

After using AZITH

Storage

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

Disposal

The hospital staff will dispose of any leftover AZITH.

Product description

What it looks like

AZITH 500 mg powder for injection is a white powder in a glass vial. The powder is dissolved and then diluted, providing 100 mg/mL solution following reconstitution.

Available in packs of 1 vial.

Ingredients

Active ingredient:

Each AZITH vial contains 500 mg azithromycin.

Inactive ingredients:

- sodium hydroxide
- anhydrous citric acid.

AZITH 500 mg powder for injection does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Supplier

AZITH is supplied in Australia by:

Alphapharm Pty Limited

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian Registration Number:

AZITH 500 mg: AUST R 146755

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