

## **Arrow - Azithromycin**

Azithromycin 500 mg tablets

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### **What is in this leaflet**

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This leaflet answers some common questions about ARROW - AZITHROMYCIN.

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 your taking ARROW - AZITHROMYCIN 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.

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### **What ARROW - AZITHROMYCIN is used for**

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ARROW - AZITHROMYCIN contains azithromycin monohydrate. It is an antibiotic that belongs to a group of medicines called azalides, a sub-class of macrolide antibiotics. Azithromycin works by killing or stopping the growth of bacteria causing your infection.

ARROW - AZITHROMYCIN are used to treat bacterial infections such as

- respiratory infections eg bronchitis, pneumonia, sinusitis, pharyngitis, tonsillitis and otitis media
- skin and skin structure infections including abscess and ulcers
- sexually transmitted diseases eg chlamydia or gonorrhoea
- pelvic inflammatory disease (infection and inflammation of uterus, fallopian tubes and ovaries)
- an uncommon eye infection (*Chlamydia trachomatis* conjunctivitis and trachoma).

Like other antibiotics, ARROW - AZITHROMYCIN does not work against viral infections such as colds or flu.

ARROW - AZITHROMYCIN can be used to prevent infection due to *Mycobacterium avium-intracellulare* complex disease in HIV-infected patients.

Your doctor may have prescribed ARROW - AZITHROMYCIN for another purpose. Ask your doctor if you have any questions about why ARROW - AZITHROMYCIN has been prescribed for you.

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

There is no evidence that ARROW - AZITHROMYCIN is addictive.

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## **Before you take ARROW - AZITHROMYCIN**

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### ***When you must not take it***

**Do not take ARROW - AZITHROMYCIN if you are allergic to:**

- **medicines containing azithromycin**
- **any other macrolide or ketolide antibiotics (eg clarithromycin, erythromycin, roxithromycin, telithromycin)**
- **any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include wheezing, shortness of breath or difficulty breathing; swelling of the face, lips or tongue that may cause difficulty in swallowing or breathing; hives, itching or skin rash.

**Do not take ARROW - AZITHROMYCIN if the packaging is torn or shows signs of tampering.**

**Do not take ARROW - AZITHROMYCIN if the expiry date (Exp.) printed on the pack has passed.**

It may not work as well if you do.

### **Before you start to take it**

**Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.**

**Tell your doctor if you have liver, kidney or heart problems, or any other medical conditions.**

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

Your doctor will discuss the risks and benefits of taking ARROW - AZITHROMYCIN during pregnancy.

**Tell your doctor if you are breastfeeding or intend to breastfeed.**

Your doctor will discuss the risks and benefits of taking ARROW - AZITHROMYCIN when breastfeeding.

**If you have not told your doctor about any of the above, tell him/her before you start taking ARROW - AZITHROMYCIN.**

### ***Taking other medicines***

**Tell your doctor if you are taking any other medicines, including those you buy from a pharmacy, supermarket or health food shop.**

Some medicines may be affected by ARROW - AZITHROMYCIN, or may affect how well it works. These include:

- antacids (medicines used to relieve indigestion and heartburn)
- coumarin-type oral anticoagulants (eg warfarin, used to prevent blood clots)
- cyclosporin (a medicine used to prevent organ transplant rejection or to treat certain problems with the immune system)
- digoxin (a medicine used to treat atrial fibrillation and heart failure)
- ergot derivatives (eg ergotamine, used to treat migraines)
- terfenadine or astemizole (medicines used to treat hayfever and allergies)
- zidovudine (medicine used to treat patients with AIDS)
- oral contraceptives (some antibiotics may decrease the effectiveness of some birth control pills, although this has not been shown with ARROW - AZITHROMYCIN. Talk to your doctor about the need for additional contraception).

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking ARROW - AZITHROMYCIN.

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## How to take ARROW - AZITHROMYCIN

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

They may differ from the information contained in this leaflet.

### ***How much to take***

Take ARROW - AZITHROMYCIN exactly as your doctor has prescribed.

Your doctor will tell you how many tablets you need to take. This depends on the type of your infection:

- **Chlamydia or gonorrhoea:** two tablets taken as a single dose.
- **Other infections:** tablets are usually taken once a day. Sometimes the dose is taken once a week.

The dose for your child will depend on his or her body weight and the type of infection being treated.

***How to take it***

**Swallow ARROW - AZITHROMYCIN tablets with a glass of water.**

***When to take it***

ARROW - AZITHROMYCIN can be taken with or without food.

**If you are taking an antacid (eg *Gastrogel, Mylanta*), take it at least one hour before or two hours after your ARROW - AZITHROMYCIN dose.**  
This will avoid any possible effect of the antacid on the absorption of ARROW - AZITHROMYCIN.

***How long to take it***

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

***If you forget to take it***

**If you are taking ARROW - AZITHROMYCIN 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.**

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose that you missed.**

**If you have trouble remembering to take your medicine, ask your pharmacist for some hints.**

**If you take too much ARROW - AZITHROMYCIN (overdose)**

**Immediately telephone your doctor, or the National Poisons Information Centre (0800 POISON or 0800 764 766), or go to Accident and Emergency department at your nearest hospital, if you think that you or anyone else may have taken too much ARROW - AZITHROMYCIN.**

**Do this even if there are no signs of discomfort or poisoning.**  
You may need urgent medical attention.

Symptoms of an overdose may include upset stomach, diarrhoea or skin rashes.

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**While you are taking ARROW - AZITHROMYCIN**

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***Things you must do***

**Before starting any new medicine, tell your doctor or pharmacist that you are taking ARROW - AZITHROMYCIN.**

**Tell all doctors, dentists and pharmacists who are treating you that you are taking ARROW - AZITHROMYCIN.**

**Tell your doctor if you become pregnant while taking ARROW - AZITHROMYCIN.**

**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 immediately. Do this even if it occurs several weeks after ARROW - AZITHROMYCIN 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 ARROW - AZITHROMYCIN, 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 antibiotic allows yeast to grow and the above symptoms to occur. ARROW - AZITHROMYCIN does not work against yeast.

**Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.**

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

### ***Things you must not do***

**Do not stop taking ARROW - AZITHROMYCIN or change the dose without first 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, which may cause your infection to return or not clearing completely.

**Do not give ARROW - AZITHROMYCIN to anyone else, even if they have the same condition as you.**

**Do not use ARROW - AZITHROMYCIN to treat other complaints unless your doctor tells you to.**

### ***Things to be careful of***

**Protect your skin when you are in the sun, especially between 10 am and 3 pm.**

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.**

**Talk to your doctor about the need for additional contraception while taking ARROW - AZITHROMYCIN.**

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

**Be careful driving or operating machinery until you know how ARROW - AZITHROMYCIN affects you.**

ARROW - AZITHROMYCIN may cause dizziness and fatigue in some people. If you have any of these symptoms, do not drive or operate machinery, or do anything else that could be dangerous.

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## **Side Effects**

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

Like all other medicines, ARROW - AZITHROMYCIN may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

**Tell your doctor 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, loose bowel motions
- dizziness, headache, spinning sensation
- tiredness, drowsiness
- muscle or joint aches
- hearing loss or ringing in the ears
- altered taste and smell.

**Tell your doctor immediately and before you take your next dose of ARROW - AZITHROMYCIN if you notice any of the following:**

- severe persistent diarrhoea (loose bowel motions)

- fast or irregular heartbeats
- chest pain
- symptoms of sunburn such as redness, itching, swelling or blistering that may occur more quickly than normal
- hives, itching or skin rash
- fainting
- yellowing of the eyes or skin, also called jaundice
- 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
- blood in the urine or bowel motions
- convulsions (fits)
- severe upper stomach pain, often with nausea and vomiting.

These symptoms are usually rare, but may be serious and need urgent medical attention.

**Tell your doctor immediately or go to your nearest Accident and Emergency Centre if you notice symptoms of allergic reactions including:**

- sudden swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- severe skin reactions with blistering or peeling of the skin, severe skin rash or itching.

***After finishing ARROW - AZITHROMYCIN***

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with ARROW - AZITHROMYCIN:

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

These are rare but serious side effects. You may need urgent medical attention. **Do not take any medicine for this diarrhoea without first checking with your doctor.**

ARROW - AZITHROMYCIN can cause some bacteria, which are normally present in the bowel and normally harmless, to multiply and therefore cause the above symptoms.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known. Tell your doctor if you notice anything that is making you feel unwell.

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## **After taking ARROW - AZITHROMYCIN**

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### ***Storage***

**Keep ARROW - AZITHROMYCIN in a safe place 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.

**Keep ARROW - AZITHROMYCIN in a cool, dry place where the temperature stays below 25°C.**

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

If you take the tablets out of the blister or the carton, they may not keep well.

**Do not store ARROW - AZITHROMYCIN or any other medicine in a bathroom or near a sink. Do not leave it in the car or on window sills.**

Heat and dampness can destroy some medicines.

### ***Disposal***

If your doctor tells you to stop taking ARROW - AZITHROMYCIN, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

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## **Product Description**

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### ***What it looks like***

ARROW - AZITHROMYCIN is a white to off-white, film-coated, capsule-shaped, biconvex tablet, with ">" on one side and "AT|500" on the other side.

ARROW - AZITHROMYCIN is available in a blister pack of 2 tablets.

### ***Ingredients***

The active ingredient in ARROW - AZITHROMYCIN is azithromycin (as monohydrate). Each tablet contains 500 mg of azithromycin.

The tablets also contain:

- calcium phosphate
- pregelatinised maize starch
- croscarmellose sodium
- sodium lauryl sulfate
- magnesium stearate
- Opadry AMB White OY-B-28920.

The tablets do not contain sucrose, tartrazine or any azo dyes.

***Sponsor***

ARROW - AZITHROMYCIN is distributed in New Zealand by:

**Arrow Pharmaceuticals (NZ) Limited**

Mount Eden Central Business Park,  
33a Normanby Road, Mt. Eden  
Auckland, New Zealand

***Date of preparation***

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