

# AZITHROMYCIN-AFT

## 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 using AZITHROMYCIN-AFT?

AZITHROMYCIN-AFT contains the active ingredient azithromycin (as dihydrate). AZITHROMYCIN-AFT is used to treat pneumonia, a lung infection caused by certain bacteria including *Legionella pneumophila*.

For more information, see Section [1. Why am I using AZITHROMYCIN-AFT?](#) in the full CMI.

### 2. What should I know before I use AZITHROMYCIN-AFT?

Do not use if you have ever had an allergic reaction to AZITHROMYCIN-AFT or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

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

### 3. What if I am taking other medicines?

Some medicines may interfere with AZITHROMYCIN-AFT 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-AFT given?

- Your doctor will decide how much AZITHROMYCIN-AFT you should receive and for how long you should receive it.
- The usual dose of AZITHROMYCIN-AFT is 500 mg given as an injection into a vein for 2 – 5 days.

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

### 5. What should I know while using AZITHROMYCIN-AFT?

<b>Things you should do</b>	<ul style="list-style-type: none"> <li>Remind any doctor, dentist, pharmacist or nurse you visit that you are using AZITHROMYCIN-AFT.</li> <li>If your infection does not improve within a few days, or if your symptoms become worse, tell your doctor.</li> <li>If you get severe diarrhoea, tell your doctor, pharmacist or nurse immediately; even if it occurs weeks after your treatment with AZITHROMYCIN-AFT has stopped.</li> <li>If you get a sore, white mouth or tongue during or after stopping treatment with AZITHROMYCIN-AFT, tell your doctor, pharmacist or nurse; also tell them if you get vaginal itching or discharge.</li> <li>While on this treatment, protect your skin when you are in the sun, especially between 10am and 3pm</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>Do not stop using this medicine or lower the dosage without checking with your doctor first.</li> <li>If you do not complete the full course, your infection may not clear completely or may return.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>AZITHROMYCIN-AFT is stored by hospital staff in the pharmacy or in the ward.</li> <li>This medicine is kept below 30 °C.</li> </ul>

For more information, see Section [5. What should I know while using AZITHROMYCIN-AFT?](#) in the full CMI.

### 6. Are there any side effects?

- Very serious side effects:** related to [allergic reaction](#) (sudden onset of: rash, itching/hives, swelling of face/lips/tongue/other parts of body, shortness of breath, wheezing/trouble breathing; occurring after fever: blisters/ulcers on skin/in mouth/airways), [convulsions](#), [gastrointestinal](#) (diarrhoea [bloody/mucous], stomach pain, fever), [heart](#) (chest pain, fainting), [liver](#) (eyes/skin turning yellow). **Go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**
- Serious side effects:** related to [blood](#) (bleeding/bruising easier than normally, red/purple blotches under skin), [gastrointestinal](#) (sever ongoing diarrhoea/upper stomach pain [often with nausea & vomiting], dark stools/blood in stools), [heart](#) (fast/irregular heartbeat), [infection](#) (fever, severe chills, sore throat, mouth ulcers), [mental state](#) (aggressiveness, nervousness, [renal](#) (dark urine/blood in urine), [skin](#) (symptoms of sunburn [redness, itching, swelling, blistering] quicker than usual, decreased feeling/sensitivity especially of skin, hives/itching/skin rash, widespread body rash, fever, swollen lymph nodes). **Call your doctor straight away if you notice any of these serious side effects.**
- Common side effects:** related to [pain](#) (pain/inflammation at infusion site, muscle/joint aches), [gastrointestinal](#) (nausea, loss of appetite, vomiting, stomach pain, indigestion, wind, constipation, loose stools), [thrush](#) (oral: white, furry, sore tongue/mouth; vaginal: sore, itchy vagina with/without white discharge), [alertness/orientation](#) (dizziness, headache, spinning sensation, tiredness, drowsiness, fatigue), [sense](#) (hearing loss/ringing in ears, altered taste/smell), [skin](#) (rash). **Speak to your doctor if you have any of these less serious side effects and they worry you.**

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-AFT

Active ingredient(s): *azithromycin* (a-zithro-my-sin)

## Consumer Medicine Information (CMI)

This leaflet provides important information about using AZITHROMYCIN-AFT. **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-AFT.**

Where to find information in this leaflet:

1. [Why am I using AZITHROMYCIN-AFT?](#)
2. [What should I know before I use AZITHROMYCIN-AFT?](#)
3. [What if I am taking other medicines?](#)
4. [How is AZITHROMYCIN-AFT given?](#)
5. [What should I know while using AZITHROMYCIN-AFT?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

## 1. Why am I using AZITHROMYCIN-AFT?

AZITHROMYCIN-AFT contains the active ingredient **azithromycin (as dihydrate)**. AZITHROMYCIN-AFT 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-AFT works by killing or stopping the growth of bacteria causing your infection. AZITHROMYCIN-AFT will not work against viral infections such as colds or flu.

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

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

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

AZITHROMYCIN-AFT is not addictive.

## 2. What should I know before I use AZITHROMYCIN-AFT?

### Warnings

**Do not use AZITHROMYCIN-AFT if:**

- you are allergic to azithromycin, any other ketolide or macrolide antibiotic or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of

the face/lips/tongue or to other parts of the body, skin rash, itching or hives.

**Check with your doctor if you:**

- have any other medical conditions:
  - kidney problems
  - liver problems
  - heart problems, including abnormal rhythm
  - muscle weakness
  - low levels of potassium or magnesium in your blood
- take any medicines for any other condition
- have allergies to any other medicines, foods, preservatives or dyes.

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

Check with your doctor if you are pregnant or intend to become pregnant.

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

## Allergy to ketolide or macrolide antibiotic

- The active ingredient, azithromycin, belongs to the sub-class of antibiotic called azalide. Azalide belongs to the umbrella group of antibiotics called macrolides; another sub-class of macrolides is called ketolides.
- Therefore, if you are allergic to ingredients in any of the sub-classes of macrolides (e.g. roxithromycin, erythromycin, clarithromycin, telithromycin) you may be allergic to AZITHROMYCIN-AFT.
- Check with your doctor if you are not sure whether you are allergic to any of the ingredients listed above.

## 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.

**Medicines that should not be taken together with AZITHROMYCIN-AFT:**

- Antacids (medicine used to treat indigestion)
- Ergot derivatives (like ergotamine, used to treat migraines).

When taken together with AZITHROMYCIN-AFT, these medicines may interfere with your treatment and possibly be dangerous to your health.

**Some medicines may interfere with AZITHROMYCIN-AFT and affect how it works:**

- Coumarin-type oral anticoagulants (medicines used to prevent blood clots)
- Cyclosporin (medicine used to prevent organ transplant rejection or to treat certain problems with the immune system)
- Terfenadine or astemizole (medicines used to treat allergies and hay fever)
- Zidovudine (medicine used to treat patients with AIDS)
- Diphenoxylate (Lomotil) (medicine used to treat diarrhoea)
- Some medicines used to treat heart rhythm problems, 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.

This medicine may be affected by AZITHROMYCIN-AFT, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

**Medicines that may increase the effect of AZITHROMYCIN-AFT include:**

- Colchicine (medicine used to treat gout)
- Digoxin (medicine used to treat abnormal heart rhythm or heart failure).

You may need different amounts of your medicines, or you may need to take different medicines.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect AZITHROMYCIN-AFT.**

## 4. How is AZITHROMYCIN-AFT given?

### How much is given

- Your doctor will decide how much AZITHROMYCIN-AFT you should receive and for how long you should receive it.
- The usual dose of AZITHROMYCIN-AFT is 500 mg given as an injection into a blood vessel for 2 – 5 days. You may then be given 500 mg AZITHROMYCIN-AFT by mouth once a day for another 2 – 7 days (to complete a 7- to 10-day course of antibiotics).
- Follow the instructions provided when AZITHROMYCIN-AFT was prescribed, including the number of days it should be taken.

### How AZITHROMYCIN-AFT is given

- AZITHROMYCIN-AFT is given as an injection by a doctor or trained nurse.
- AZITHROMYCIN-AFT is a powder which is mixed with Water for Injections and then diluted by the

pharmacist. It is then injected into a blood vessel which takes around 60 minutes.

### If too much AZITHROMYCIN-AFT is given

AZITHROMYCIN-AFT is given under the close supervision of your doctor; therefore, it is very unlikely that you will receive too much.

If you think that you have received too much AZITHROMYCIN-AFT, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

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

## 5. What should I know while using AZITHROMYCIN-AFT?

### Things you should do

**If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.**

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

#### Call your doctor straight away if you:

- **If you get severe diarrhoea, tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after AZITHROMYCIN-AFT 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 being given, or soon after stopping AZITHROMYCIN-AFT, 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-AFT allows yeast to grow and the above symptoms to occur. AZITHROMYCIN-AFT does not work against yeast.

- **If you become pregnant while being given AZITHROMYCIN-AFT, tell your doctor.**
- **Tell your doctor immediately if during treatment with AZITHROMYCIN-AFT your baby develops irritability with feeding or starts vomiting.**

This may be a sign of a stomach disorder in the infant.

- **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.

Remind any doctor, dentist, pharmacist or nurse you visit that you are using AZITHROMYCIN-AFT.

### Things you should not do

- Do not stop using this medicine or lower to dosage without checking with your doctor first.  
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-AFT to anyone else, even if they have the same condition as you.
- Do not use AZITHROMYCIN-AFT to treat any other medical complaints unless your doctor tells you to.

### Driving or using machines

AZITHROMYCIN-AFT is not expected to affect your ability to drive a car or operate machinery.

### Drinking alcohol

Alcohol is not expected to have any effect on the use of AZITHROMYCIN-AFT.

### Looking after your medicine

- AZITHROMYCIN-AFT is stored by hospital staff in the pharmacy or in the ward
- This medicine is kept below 30 °C.

### When to discard your medicine (as relevant)

The hospital staff will dispose of any leftover AZITHROMYCIN-AFT.

## 6. Are there any side effects?

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
<b>Alertness- and orientation-related:</b> <ul style="list-style-type: none"> <li>• Dizziness</li> <li>• Headache</li> <li>• Spinning sensation</li> <li>• Tiredness</li> <li>• Drowsiness</li> <li>• Fatigue</li> </ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

Less serious side effects	What to do
<b>Gastrointestinal-related:</b> <ul style="list-style-type: none"> <li>• Nausea (feeling sick)</li> <li>• Loss of appetite</li> <li>• Vomiting</li> <li>• Stomach pain</li> <li>• Indigestion</li> <li>• Wind</li> <li>• Constipation</li> <li>• Loose stools</li> </ul> <b>Pain-related:</b> <ul style="list-style-type: none"> <li>• Pain/inflammation at site of infusion, or pain during infusion</li> <li>• Muscle or joint aches</li> </ul> <b>Sense-related:</b> <ul style="list-style-type: none"> <li>• Hearing loss</li> <li>• Ringing in the ears</li> <li>• Altered taste/smell</li> </ul> <b>Skin-related:</b> <ul style="list-style-type: none"> <li>• Rash</li> </ul> <b>Thrush-related:</b> <ul style="list-style-type: none"> <li>• Oral thrush (white, furry, sore tongue and mouth)</li> <li>• Vaginal thrush (sore, itchy vagina and/or white discharge)</li> </ul>	

### Serious side effects

Serious side effects	What to do
<b>Blood-related:</b> <ul style="list-style-type: none"> <li>• Bleeding/bruising more easily than normal</li> <li>• Red/purple blotches under the skin</li> </ul> <b>Gastrointestinal-related:</b> <ul style="list-style-type: none"> <li>• Severe ongoing diarrhoea</li> <li>• Severe upper stomach pain, often with nausea and vomiting</li> <li>• Dark stools or blood in the stools</li> </ul> <b>Heart-related:</b> <ul style="list-style-type: none"> <li>• Fast or irregular heart beat</li> </ul> <b>Infection-related:</b> <p><u>Signs of frequent or worrying infections, such as:</u></p> <ul style="list-style-type: none"> <li>• Fever</li> <li>• Severe chills</li> <li>• Sore throat</li> <li>• Mouth ulcers</li> </ul> <b>Mental state-related:</b> <ul style="list-style-type: none"> <li>• Aggressive reaction</li> <li>• Nervousness</li> <li>• Agitation</li> <li>• Anxiety</li> </ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

Serious side effects	What to do
<p><b>Renal-related:</b></p> <ul style="list-style-type: none"> <li>• Dark urine</li> <li>• Blood in the urine</li> </ul> <p><b>Skin-related:</b></p> <ul style="list-style-type: none"> <li>• Symptoms of sunburn (i.e. redness, itching, swelling, blistering) which may occur more quickly than normal</li> <li>• Decreased feeling or sensitivity, especially in the skin</li> <li>• Hives, itching or skin rash</li> <li>• Widespread body rash, fever and swollen lymph nodes</li> </ul>	

### Very serious side effects

Very serious side effects	What to do
<p><b>Allergic reaction:</b> <u>Sudden signs of allergy such as:</u></p> <ul style="list-style-type: none"> <li>• Rash</li> <li>• Itching/hives on the skin</li> <li>• Swelling of the face, lips, tongue or other parts of the body</li> <li>• Shortness of breath</li> <li>• Wheezing or trouble breathing</li> </ul> <p><u>Occurring after a period of fever:</u></p> <ul style="list-style-type: none"> <li>• Blisters/ulcers on the skin, in the mouth or airways</li> </ul> <p><b>Convulsions (fits)</b></p> <p><b>Gastrointestinal-related:</b></p> <ul style="list-style-type: none"> <li>• Diarrhoea, usually with blood and mucous</li> <li>• Stomach pain</li> <li>• Fever</li> </ul> <p><b>Heart-related:</b></p> <ul style="list-style-type: none"> <li>• Chest pain</li> <li>• Fainting</li> </ul> <p><b>Liver-related:</b></p> <ul style="list-style-type: none"> <li>• Eyes/skin turning yellow (jaundice)</li> </ul>	<p><b>Go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</b></p>

**Tell your doctor 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.

### 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](http://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-AFT contains

<b>Active ingredient (main ingredient)</b>	Azithromycin dihydrate
<b>Other ingredients (inactive ingredients)</b>	Citric acid monohydrate Sodium hydroxide (to adjust pH)

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

### What AZITHROMYCIN-AFT looks like

AZITHROMYCIN-AFT is a white, freeze-dried powder and is supplied in a 10 mL glass vial.

AZITHROMYCIN-AFT will be made up with a suitable solution before it is being given to you. The made-up medicine will be a clear and colourless solution and have no visible particles.

AUST R 334520

### Who distributes AZITHROMYCIN-AFT

AFT Pharmaceuticals Pty Ltd

113 Wicks Road

North Ryde

NSW 2113

Email: [customer.service@aftp pharm.com](mailto:customer.service@aftp pharm.com)

Freephone (AU): 1800 AFTP HARM (1800 238 74276)

This leaflet was prepared in August 2021.