Zithromax ® IV

azithromycin

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 Zithromax IV?

Zithromax IV contains an 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 Zithromax IV? in the full CMI.

2. What should I know before treatment with Zithromax IV?

You should not be given Zithromax IV 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 you 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 Zithromax IV? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Zithromax IV and affect how it works. A list of these medicines is in Section <u>3. What if I am taking other medicines?</u> in the full CMI.

4. How is Zithromax IV given?

Zithromax IV is given as a slow infusion "drip" into a vein by a doctor or nurse. More instructions can be found in Section <u>4. How is Zithromax IV given?</u> in the full CMI.

5. What should I know during treatment with Zithromax IV?

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; you have chest pain; shortness of breath; dizzines; light-headedness; numbness; severe diarrhoea; sore white mouth or tongue during or after stopping treatment; vaginal itching or discharge. Talk to your doctor about the need for additional method of contraception; if you become pregnant; if you breastfeed. Alert your doctor immediately ifyou experience problems with your hearing; or, if your baby develops irritability with feeding or starts vomiting. Tell all doctors, dentists or pharmacists who are treating you that you are being given Zithromax IV. For more information on "Things you should do" can be found in Section 5 in the full CMI. 	
Things you should not do	Do not breastfeed your baby without discussing the risks with your doctor.	
Looking after your medicine	Zithromax IV is stored in the pharmacy or on the hospital ward under the correct conditions.	

For more information, see Section 5. What should I know during treatment with Zithromax IV? in the full CMI.

6. Are there any side effects?

Side effects of this medicine may include pain at injection site; oral/vaginal thrush; nausea; vomiting; loss of appetite; fever; diarrhoea; stomach pain; constipation; indigestion; dizziness; headache; spinning sensation; drowsiness; fatigue; restlessness; 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; muscle pain; numbness or weakness; trouble speaking, understanding or walking; loss of balance; lack of coordination; abnormal hearing; altered vision, taste/smell; 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.

Zithromax IV®

Azithromycin

Consumer Medicine Information (CMI)

This leaflet provides important information about using Zithromax IV. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about treatment with Zithromax IV.

Where to find information in this leaflet:

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

1. Why am I being treated with Zithromax IV?

Zithromax IV contains the active ingredient azithromycin.

It 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.

Zithromax IV 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.

Zithromax IV will not work against viral infections such as colds or flu

Your doctor may have prescribed Zithromax IV for another reason.

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

2. What should I know before treatment with Zithromax IV?

Warnings

Zithromax IV should not be given to you if:

 you are allergic to azithromycin any other ketolide or macrolide antibiotic (e.g., roxithromycin, erythromycin, clarithromycin, telithromycin), or citric

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 rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or troubled 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:

- any kidney problems
- any liver problems
- any 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 <u>6</u>. <u>Are there any side effects</u>?

Pregnancy and breastfeeding

Talk to your doctor if you are pregnant, or intend 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 them before you are given Zithromax IV.

Use in children

The safety and effectiveness of Zithromax IV in children have not been established.

There is no evidence that Zithromax IV is addictive.

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 Zithromax IV. 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 Zithromax IV 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 Zithromax IV.

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

4. How is Zithromax IV given?

How much is given

Your doctor will decide how much Zithromax IV you should receive and the length of time for which you should receive it.

The usual dose of Zithromax IV is 500 mg for 2 to 5 days. You may then be given 500 mg oral Zithromax once a day for another 2 - 7 days (to complete a 7 to 10 day course of antibiotics).

How is Zithromax IV given

Zithromax IV is given through slow infusion "drip" into a vein by your doctor or nurse over a period about 60 minutes.

If you receive too much Zithromax IV

As Zithromax IV 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, especially abnormal hearing, tell your doctor or nurse immediately.

Tell your doctor or nurse immediately if you are concerned that you may have been given too much Zithromax IV.

5. What should I know during treatment with Zithromax IV?

Things you should do

Tell any doctor or nurse 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 Zithromax IV 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 Zithromax IV
- you get vaginal itching or discharge.

This may mean you have a yeast infection called thrush. Sometimes the use of Zithromax IV allows yeast to grow and the above symptoms to occur. Zithromax IV does not work against yeast.

- you realise that you are pregnant while being given Zithromax IV
- during treatment with Zithromax IV your baby develops irritability with feeding or starts vomiting.

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

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

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

Things you should not do

Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting with a pharmacist.

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.

Zithromax IV 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 Zithromax IV 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.

Driving or using machines

Be careful driving or operating machinery until you know how Zithromax IV affects you. Whilst it is unlikely that you will drive or operate machinery when having Zithromax IV, you need to be aware that Zithromax IV 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

Zithromax IV is stored in the pharmacy or on the hospital ward under the correct conditions.

Disposal of Zithromax IV

The hospital staff will dispose of any leftover Zithromax IV.

6. Are there any side effects?

Tell your doctor or nurse as soon as possible if you do not feel well while you are having treatment with Zithromax IV.

Zithromax IV 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 vaginal thrush - sore and itchy vagina and/or white discharge nausea, 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. 	Speak to your nurse or doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
 diarrhoea, usually with blood and mucus, stomach pain and fever severe upper stomach pain, often with nausea and vomiti fast or irregular heart beat, palpitations chest pain sudden dizziness or lightheadedness 	nurse or doctor straight away if you notice any

Serious side effects		What to do
•	cold sweat 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	
•	widespread body rash, fever and swollen lymph nodes	
•	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	
•	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	
•	blisters or ulcers on the skin, in the mouth or airways 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, arm, leg or shoulder	
•	numbness or weakness in the face, arm, or leg	
•	trouble with speech, or understanding speech	
•	aggressive reaction, nervousness, agitation or anxiety	
•	problems with vision	
•	trouble walking, loss of balance, or lack of coordination fainting	
•	convulsions (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.

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 Zithromax IV.

- 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.

Zithromax IV 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.

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

Do not be alarmed by the lists of possible side effects. You may not experience any of them.

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 Zithromax IV contains

Active ingredient	Azithromycin
(main ingredient)	
Other ingredients	sodium hydroxide
(inactive ingredients)	citric acid

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

Each Zithromax IV vial contains 500 mg of azithromycin as the active ingredient.

What Zithromax IV looks like

Zithromax IV is a white to off-white powder supplied in a glass vial.

Aust R 91913

Who distributes Zithromax IV

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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