

DBL™ Azithromycin for Injection

Azithromycin (a-ZITH-ro-my-sin)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL™ Azithromycin for Injection. 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 you taking DBL™ Azithromycin for Injection 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 your medicine.

You may need to read it again.

What DBL™ Azithromycin for Injection is used for

DBL™ Azithromycin for Injection is used to treat Pneumonia, a lung infection caused by certain bacteria including *Legionella pneumophila*.

Azithromycin 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.

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

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

Ask your doctor if you have any questions about why DBL™

Azithromycin for Injection has been prescribed for you.

Your doctor may have prescribed it for another reason.

DBL™ Azithromycin for Injection is only available with a doctor's prescription.

This medicine is not addictive.

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

Before you are given DBL™ Azithromycin for Injection

When you must be given it

You must not be given DBL™ Azithromycin for Injection if you are allergic to:

- azithromycin
- any other macrolide or ketolide antibiotics (e.g., clarithromycin, erythromycin, roxithromycin, 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.

Do not take this medicine if the expiry date (EXP) printed on the packaging 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 start taking this medicine, 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 have any other health problems, including:

- any liver problems
- any kidney problems
- any heart problems.
- a fungal infection
- inflammation of the large bowel

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

Your doctor will discuss the possible risks and benefits of being given Azithromycin during pregnancy.

Tell your doctor if you are breast-feeding or plan to breastfeed.

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

If you have not told your doctor about any of the above, tell them before you start taking Azithromycin.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you

get without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may interfere with DBL™ Azithromycin for Injection. These include:

- ergot derivatives (such as ergotamine, which is used to treat migraines)
- antacids, medicines used to treat heartburn and indigestion
- coumarin-type oral anti-coagulants (a medicine used to prevent blood clots eg warfarin)
- cyclosporin (a medicine used to prevent organ transplant rejection or to treat certain problems with the immune system)
- digoxin (a medicine used to treat heart failure)
- terfenadine or astemizole (medicines used to treat allergies)
- zidovudine, a medicine used to treat patients with AIDS

These medicines may be affected by Azithromycin 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 to avoid while taking Azithromycin.

Talk to your doctor about the need for additional contraception while taking DBL™

Azithromycin for Injection.

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

How to take DBL™ Azithromycin for Injection

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

They may differ from the information contained in this leaflet.

If you do not understand these instructions, ask your doctor or pharmacist for help.

How much you will be given

Your doctor will decide how much Azithromycin you should receive and the length of time for which you should receive it. The usual dose of Azithromycin is 500 mg given as an injection into a vein for 2 to 5 days.

You may then be given 500 mg oral Azithromycin once a day for another 2 - 7 days (to complete a 7 to 10 day course of antibiotics).

Your doctor will decide the right dose for you.

How to take it

Continue taking Azithromycin until you finish the course or until your doctor recommends.

Do not stop taking it because you are feeling better.

If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.

If you take too much (Overdose)

As DBL™ Azithromycin 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 Poisons Information Centre (telephone in Australia - 13 11 26; in New Zealand 0800 764 766) for advice if you think that you or anyone else may have

taken too much DBL™ Azithromycin for Injection. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are receiving DBL™ Azithromycin for Injection

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 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 DBL™ Azithromycin for Injection, 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 this medicine allows yeast to grow and the above symptoms to occur. Azithromycin does not work against yeast.

If you become pregnant while taking DBL™ Azithromycin for Injection, tell your doctor.

If you are about to start any new medicines, tell your doctor and pharmacist that you are taking DBL™ Azithromycin for Injection.

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

Things you must not do

Do not stop taking Azithromycin 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 DBL™ Azithromycin for Injection to anyone else, even if they have the same condition as you.

Do not use DBL™ Azithromycin for Injection to treat any other medical complaints unless your doctor tells you to.

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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking DBL™ Azithromycin for Injection.

Like other medicines, Azithromycin 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 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 you are receiving it

Tell your doctor or pharmacist if you notice any of the following 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, 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 if you notice any of the following:

- severe persistent diarrhoea (loose bowel motions)
- fast or irregular heart beat
- chest pain
- symptoms of sunburn such as redness, itching, swelling or blistering which may occur more quickly than normal
- severe blistering or peeling of the skin
- difficulty breathing
- swelling of the face, lips or tongue
- 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 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.

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 DBL™ Azithromycin for Injection:

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

Azithromycin 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.

After using DBL™ Azithromycin for Injection

Storage

DBL™ Azithromycin for Injection 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 product.

Product description

What it looks like

DBL™ Azithromycin for Injection is a white or almost white powder in a glass vial.

Ingredients

A vial of DBL™ Azithromycin for Injection contains 500 mg of azithromycin (as monohydrate) as the active ingredient.

It also contains:

- citric acid
- sodium hydroxide

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

Sponsor

DBL™ Azithromycin for Injection is supplied by:

Pfizer Australia Pty Ltd
38 – 42 Wharf Road
West Ryde, NSW 2114
Australia

Toll Free number: 1800 675 229

DBL™ Azithromycin for Injection is available in the following strengths:

- 500 mg /vial AUST R 161682

This leaflet was updated in June 2017.