

# DBL™ Amikacin Injection

## 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 DBL Amikacin Injection?

DBL Amikacin Injection contains the active ingredient amikacin. Amikacin is an antibiotic that belongs to a group of medicines called aminoglycosides. It is used to treat serious bacterial infections.

For more information, see Section [1. Why am I being treated with DBL Amikacin Injection?](#) in the full CMI.

### 2. What should I know before I am treated with DBL Amikacin Injection?

You should not be given DBL Amikacin Injection if you have ever had an allergic reaction to amikacin, sulfites or any of the ingredients listed at the end of the CMI; are pregnant or breastfeeding; have myasthenia gravis; have experienced hearing loss or kidney problems with similar antibiotics.

**Talk to your doctor if you have any other medical conditions including kidney disease, hearing impairments, mitochondrial mutations, muscular disorders; take any other medicines; or plan to become pregnant or breastfeed.**

For more information, see Section [2. What should I know before I am treated with DBL Amikacin Injection?](#) in the full CMI.

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

Some medicines may interfere with DBL Amikacin Injection 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 will I be given DBL Amikacin Injection?

Your doctor will decide what dose you will receive. DBL Amikacin Injection is usually given as an injection into a muscle or as a slow drip into a vein.

More instructions can be found in Section [4. How will I be given DBL Amikacin Injection?](#) in the full CMI.

### 5. What should I know while being treated with DBL Amikacin Injection?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you being treated with DBL Amikacin Injection.</li><li>• If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given amikacin.</li><li>• If you become pregnant while being treated with Amikacin Injection, tell your doctor immediately.</li><li>• Drink lots of water and stay well hydrated.</li><li>• Tell your doctor immediately if you experience hearing problems, abnormal sounds in ears, dizziness/spinning sensation, balance problems, numbness, skin tingling, muscle twitching.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how DBL Amikacin Injection affects you.</li></ul>

For more information, see Section [5. What should I know while being treated with DBL Amikacin Injection?](#) in the full CMI.

### 6. Are there any side effects?

Pain at the injection site; joint pain, muscle pain or weakness; feeling sick, vomiting; decreased appetite, weight loss; fever; rash, itchy skin, red/purple spots; tiredness; hair loss; increased saliva; generalised burning sensation; depression.

Tell your doctor as soon as possible if you notice: dizziness/spinning sensation, problems with balance; lightheadedness; headaches, shortness of breath, nosebleeds; looking pale; hearing problems, ringing/unusual sounds in the ears, loss of hearing; loss of vision, visual disturbances; rapid eye movements; passing less urine/wee than is normal or with blood; thrush; severe stomach pain and diarrhoea; numbness, skin tingling, muscle twitching and convulsions, paralysis; severe confusion; a feeling of fullness, discomfort or swelling in the upper stomach area, and yellowing of the skin and eyes and dark wee; signs of an allergic reaction (rash, itching/hives on the skin; swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or difficulty breathing).

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.

# DBL™ Amikacin Injection

Active ingredient(s): amikacin] (a-mi-KAY-sin)

## Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Amikacin Injection. **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 DBL Amikacin Injection.**

**Where to find information in this leaflet:**

1. [Why am I being treated with DBL Amikacin Injection?](#)
2. [What should I know before I am treated with DBL Amikacin Injection?](#)
3. [What if I am taking other medicines?](#)
4. [How will I be given DBL Amikacin Injection?](#)
5. [What should I know while being treated with DBL Amikacin Injection?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

## 1. Why am I being treated with DBL Amikacin Injection?

**DBL Amikacin Injection contains the active ingredient amikacin.** DBL Amikacin Injection is an antibiotic that belongs to a group of medicines called aminoglycosides (pronounced uh-MEE-noh-GLY-ko-sides).

**DBL Amikacin Injection is used to treat serious bacterial infections.** Amikacin works by killing bacteria or preventing their growth.

## 2. What should I know before I am treated with DBL Amikacin Injection?

### Warnings

**You must not be given DBL Amikacin Injection if:**

- you are allergic to amikacin, or any of the ingredients listed at the end of this leaflet or are allergic to sulfites

Always check the ingredients to make sure you can use this medicine.

- have experienced serious reactions (such as hearing loss or kidney problems) to amikacin, streptomycin, gentamicin, tobramycin, kanamycin, polymyxin B, colistin, cefaloradine, viomycin, or neomycin in the past
- you have myasthenia gravis, a condition in which the muscles become weak and tire easily
- you are pregnant or planning to become pregnant

Amikacin may seriously affect your developing baby if you are given it during pregnancy.

- you are breast-feeding.

Amikacin passes into breast milk and may affect your baby.

### Check with your doctor if you:

- have allergies to:
  - o any other medicines, in particular to any other antibiotic
  - o any other substances, such as food preservatives or dyes.
- have any other medical conditions, especially the following:
  - o kidney disease
  - o hearing impairment, or if you or your family have a mitochondrial mutation disease (a genetic condition), or loss of hearing due to antibiotic medicines  
Certain mitochondrial mutations may increase your risk of hearing loss with this product. Your doctor may recommend genetic testing before you are given DBL Amikacin Injection.
  - o muscular disorders e.g. myasthenia gravis, Parkinson's disease
- take any medicines for any other condition.

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

**This medicine should not be used if you are pregnant or intend to become pregnant.**

Check with your doctor if you are pregnant or intend to become pregnant. DBL Amikacin Injection may have serious effects on a developing baby.

**This medicine should not be used if you are breastfeeding or intend to breastfeed.**

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

### Use in the elderly

Kidney function should be monitored in elderly patients being treated with DBL Amikacin Injection.

## 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 DBL Amikacin Injection and affect how it works.**

These include:

- fluid tablets e.g. furosemide (frusemide), etacrynic acid

- platinum compounds used to treat cancer e.g. cisplatin
- some other antibiotics e.g. vancomycin, clindamycin, colistin, bacitracin, paromomycin, polymyxin B, cephalosporins, penicillin
- amphotericin, a medicine used to treat some fungal infections
- some medicines used to help prevent organ transplant rejection or to treat certain problems with the immune system e.g. ciclosporin, tacrolimus
- some medicines used during surgery such as general anaesthetic agents and suxamethonium
- opioid analgesics e.g. codeine, morphine, pethidine, fentanyl
- thiamine (vitamin B1)
- medicines used to treat loss of bone mass e.g. bisphosphonates
- indometacin, an anti-inflammatory medicine.

These medicines may be affected by DBL Amikacin Injection or may affect how well it works. 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 DBL Amikacin Injection.**

## 4. How will I be given DBL Amikacin Injection?

### How much is given

Your doctor will decide what dose you will receive and how often. This depends on your condition and other factors, such as your weight and kidney function.

### How is it given

DBL Amikacin Injection is usually given as an injection into a muscle. DBL Amikacin Injection can also be given as an intravenous infusion (as a slow drip into a vein).

For most infections, DBL Amikacin Injection is usually given in divided doses throughout the day.

### If you are given too much DBL Amikacin Injection

As DBL Amikacin Injection is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any severe side effects after being given DBL Amikacin Injection, **you should immediately:**

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

You may need urgent medical attention.

Symptoms of an amikacin overdose may include ringing in the ears, hearing difficulties, dizziness, skin rash, fever, headache, pins and needles in the hands and feet, problems with passing urine, and paralysis.

## 5. What should I know while being treated with DBL Amikacin Injection?

### Things you should do

**Drink lots of water and stay well hydrated.**

**If you are about to start on any new medicine, tell your doctor, dentist or pharmacist that you are receiving DBL Amikacin Injection.**

**If you plan to have surgery that needs a general anaesthetic, tell your doctor that you are receiving DBL Amikacin Injection.**

**If you become pregnant while being treated with DBL Amikacin Injection, tell your doctor immediately.**

**Tell your doctor immediately if you experience hearing problems, abnormal sounds in your ears, dizziness or a spinning sensation or problems with your balance, numbness, skin tingling or muscle twitching.**

**Remind any doctor, dentist or pharmacist you visit that you are being treated with DBL Amikacin Injection.**

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how DBL Amikacin Injection affects you.**

DBL Amikacin Injection may cause drowsiness, tiredness or dizziness in some people.

Make sure you know how you react to amikacin before you drive a car, operate machinery, or do anything else that could be dangerous and do not do so if not safe.

### Looking after your medicine

DBL Amikacin Injection will be stored in the pharmacy or on the ward.

## 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.

	What to do
<ul style="list-style-type: none"> <li>• pain at the injection site</li> <li>• joint pain, muscle pain or weakness</li> <li>• feeling sick, vomiting</li> <li>• decreased appetite, weight loss</li> <li>• headache</li> <li>• fever</li> <li>• rash, itchy skin, red/purple spots</li> <li>• tiredness</li> <li>• hair loss</li> <li>• increased saliva</li> <li>• burning sensation</li> <li>• depression</li> </ul>	<p><b>Speak to your doctor, nurse or pharmacist if you have any of these less serious side effects and they worry you.</b></p>

	What to do
<ul style="list-style-type: none"> <li>dizziness, spinning sensation (vertigo), problems with balance</li> <li>dizziness with lightheadedness</li> <li>severe headaches, shortness of breath, dizziness, and nosebleeds</li> <li>tiredness, headaches, being short of breath when exercising,</li> <li>dizziness and looking pale</li> <li>hearing problems, ringing or unusual sounds in the ears (tinnitus), loss of hearing</li> <li>loss of vision, visual disturbances</li> <li>rapid eye movements</li> <li>passing less wee/urine than is normal or with blood</li> <li>thrush (sore mouth or itching, burning and a thick, white, discharge from the vagina)</li> <li>severe stomach pain and diarrhoea</li> <li>numbness, skin tingling, muscle twitching and convulsions, paralysis</li> <li>severe confusion</li> <li>a feeling of fullness, discomfort or swelling in the upper stomach area, fatigue, nausea, and yellowing of the skin and eyes, loss of appetite and dark wee</li> <li>signs of an allergic reaction, 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 difficulty breathing.</li> </ul>	<p><b>Tell your doctor as soon as possible if you notice any of these serious side effects.</b></p>

Your doctor may request blood or urine tests to monitor your progress and determine possible side effects.

**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/safety/reporting-problems](http://www.tga.gov.au/safety/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 DBL Amikacin Injection contains

<b>Active ingredient (main ingredient)</b>	amikacin
<b>Other ingredients (inactive ingredients)</b>	sodium citrate dihydrate sodium metabisulfite water for injection
<b>Potential allergens</b>	sulfites

Each 2 mL of DBL Amikacin Injection contains amikacin sulfate equivalent to 500 mg (500,000 international units) of amikacin activity.

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

DBL Amikacin Injection does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

### What DBL Amikacin Injection looks like

DBL Amikacin Injection comes in a glass vial containing a clear, colourless to pale yellow solution free from visible particulate matter.

500 mg/2 mL x 5 vials - AUST R 49945

### Who distributes DBL Amikacin Injection

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

[www.pfizermedicalinformation.com.au](http://www.pfizermedicalinformation.com.au)

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