

DBL™ Amikacin Injection

amikacin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL Amikacin 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 being given Amikacin Injection against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet in a safe place.

You may need to read it again.

What DBL Amikacin Injection is used for

Amikacin is an antibiotic that belongs to a group of medicines called aminoglycosides (pronounced a-my-noe-GLY-koe-sides). It is used to treat serious bacterial infections.

Amikacin works by killing bacteria or preventing their growth.

Your doctor may have prescribed amikacin for another reason.

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

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

Before you are given DBL Amikacin Injection

When you must not be given it

You must not be given DBL Amikacin Injection if you have an allergy to amikacin or 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.

You must not be given DBL Amikacin Injection if you 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 must not be given DBL Amikacin Injection if you have myasthenia gravis, a condition in which the muscles become weak and tire easily.

You must not be given amikacin if you are pregnant or planning to become pregnant.

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

You must not be given amikacin if you are breast-feeding.

Amikacin passes into breast milk.

If you are not sure whether you should be given amikacin, talk to your doctor or pharmacist.

Before you are given it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines, in particular any other antibiotics
- sulfites / sulfates
- any other substances, such as foods, preservatives or dyes.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- kidney disease
- 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.
- muscular disorders (e.g. myasthenia gravis, Parkinson's disease).

If you have not told your doctor or pharmacist about any of the above, tell them before you are given amikacin.

Taking other medicines

Tell your doctor or pharmacist if you are taking/using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and amikacin may interfere with each other. These include:

- fluid tablets (e.g. furosemide (frusemide), etacrynic acid)
- platinum compounds used to treat cancer, such as cisplatin
- some other antibiotics (e.g. vancomycin, clindamycin, colistin, bacitracin, paromomycin, polymyxin B, cephalosporins, penicillins, viomycin)

- 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
- suxamethonium, a medicine used during surgery to relax muscles
- some general anaesthetic agents
- opioid analgesics (e.g. codeine, morphine, pethidine, fentanyl)
- thiamine (vitamin B1)
- bisphosphonates, medicines used to treat loss of bone mass
- indometacin, an anti-inflammatory medicine.

These medicines may be affected by amikacin, or may affect how well it works. You may need different amounts of your medicine, or you may need to take/use different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while receiving amikacin.

How DBL Amikacin Injection is given

How much is given

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

How it is given

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

DBL Amikacin Injection must only be given by a doctor or nurse.

How long it is given for

Your doctor will decide what dose and how long you will receive DBL Amikacin Injection. This depends on your infection and other factors, such as your weight. For most infections, DBL Amikacin Injection is usually given in divided doses throughout the day.

If you are given too much (overdose)

As DBL Amikacin Injection is most likely to be given to you in hospital under the supervision of your doctor, it is very unlikely that you will receive an overdose. However, if you experience severe side effects, tell your doctor immediately or go to Emergency at the nearest hospital.

In case of overdose, immediately contact the Poisons Information Centre for advice (telephone 13 11 26).

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

While you are being given DBL Amikacin Injection

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given DBL Amikacin Injection.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given DBL Amikacin Injection.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given amikacin.

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

Things to be careful of

Be careful driving or operating machinery until you know how DBL Amikacin Injection affects you.

As with other aminoglycoside medicines, amikacin may 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 if you are drowsy, tired or dizzy. If this occurs do not drive.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given DBL Amikacin Injection.

Amikacin helps most people with infections, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. If you are over 65 years of age you may have an increased chance of getting side effects.

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

Tell your doctor or nurse if you notice any of the following and they worry you:

- pain at the injection site
- feeling sick
- decreased appetite

- headache
- nausea and vomiting
- fever.

These side effects are usually mild.

Tell your doctor or nurse immediately if you notice any of the following:

- dizziness, spinning sensation (vertigo)
- hearing problems, ringing or unusual sounds in the ears (tinnitus)
- loss of vision
- passing less urine than is normal, blood in the urine
- numbness, skin tingling, muscle twitching and convulsions, paralysis
- 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.

Other side effects not listed above may occur in some patients.

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

Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

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

You may not experience any of them.

After being given DBL Amikacin Injection

Storage

DBL Amikacin Injection will usually be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

Product description

What it looks like

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

Ingredients

Active ingredients:

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

Other ingredients

- sodium citrate dihydrate

- sodium metabisulfite
- water for injection.

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

Sponsor

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

DBL Amikacin Injection is available in the following strengths and pack size:

- 500 mg/2 mL x 5 vials

AUST R 49945

Date of leaflet preparation: December 2023

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