

DBL™ Gentamicin Injection BP

gentamicin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL Gentamicin Injection BP. It does not contain all the available information. It does not take the place of talking to your healthcare professional.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given DBL Gentamicin Injection BP against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your healthcare professional.

Keep this leaflet.

You may need to read it again.

What DBL Gentamicin Injection BP is used for

Gentamicin is used to treat serious bacterial infections. It is an antibiotic that belongs to a group of medicines called aminoglycoside antibiotics. It works by killing bacteria or preventing their growth.

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

Your doctor may have prescribed gentamicin for another reason.

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

Before you are given DBL Gentamicin Injection BP

When you must not be given it

You must not be given DBL Gentamicin Injection BP if you have an allergy to:

- any medicine containing gentamicin
- or any of the ingredients listed at the end of this leaflet
- or similar medicines such as other aminoglycoside antibiotics such as tobramycin, streptomycin, amikacin, netilmicin, or neomycin.

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.

If you are not sure whether any of these apply to you, talk to your healthcare professional.

You must not be given DBL Gentamicin Injection BP if you have experienced serious reactions (such as hearing loss or kidney problems) to gentamicin, amikacin, tobramycin, or neomycin in the past.

If you are not sure whether you should be given DBL Gentamicin Injection BP, talk to your healthcare professional.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

- kidney disease or kidney problems
- hearing problems, or if you or your family have a mitochondrial mutation disease, or loss of hearing due to antibiotic medicines; certain mitochondrial mutations may increase your risk of hearing loss with this product
- muscular disorders (e.g. myasthenia gravis, Parkinson's disease (a disease affecting movement)).

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant or are breast-feeding.

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 DBL Gentamicin Injection BP.

Taking other medicines

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

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

- antibiotics to treat infection such as colistin, vancomycin, clindamycin, cephalosporins and penicillins
- water tablets (diuretics) (e.g. frusemide, etacrynic acid, bumetanide)
- cisplatin, a medicine used to treat cancer
- amphotericin, an antifungal medicine
- anaesthetics (e.g. halothane)
- muscle relaxants (e.g. suxamethonium).

These medicines may be affected by gentamicin, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your healthcare professional have more information on medicines to be careful with or avoid while receiving gentamicin.

How is DBL Gentamicin Injection BP 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 age, weight and kidney function.

How will it be given to you

DBL Gentamicin Injection BP must only be given by a doctor, nurse or other trained person. It is given as an injection into a muscle or as a slow injection into a vein (intravenously).

If you are given too much (overdose)

As DBL Gentamicin Injection BP is usually given to you in hospital under the supervision of your doctor, it is very unlikely that you will receive an overdose.

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Emergency at the nearest hospital, if you think that you or anyone else may have taken too much DBL Gentamicin Injection BP. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of a gentamicin overdose may include the side effects listed below in the 'Side Effects' section, but are usually of a more severe nature.

While you are being given DBL Gentamicin Injection BP

Things you must do

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

Things you must not do

Do not take any other medicines, whether they are prescription or over-the-counter medicines, unless they have been approved or recommended by a doctor or pharmacist who knows you are being given gentamicin.

Side effects

Tell your healthcare professional as soon as possible if you do not feel well while you are being given gentamicin or after the injection.

Gentamicin helps most people with certain 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.

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

You may not experience any of them.

Ask your healthcare professional to answer any questions you may have.

Tell your healthcare professional if you notice any of the following and they worry you:

- fever, sore mouth and gums
- nausea or vomiting
- headache
- unusual bleeding or bruising under the skin
- weight loss, loss of appetite
- weakness or tiredness
- increased salivation
- joint pain
- hair loss
- confusion
- depression
- pain at the injection site.

These side effects are usually mild.

If any of the following happen, tell your healthcare professional immediately or go to Emergency at the nearest hospital:

- signs of an allergic reaction, such 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.
- severe headache
- dizziness
- hearing problems or ringing in the ears
- problems with your balance
- decreased urination
- skin tingling, numbness, or muscle twitching
- fits (convulsions).

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. Serious side effects are rare.

Tell your healthcare professional if you notice anything that is making you feel unwell.

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

Some of these side effects can only be found when your healthcare professional does tests from time to time to check your progress.

After being given DBL Gentamicin Injection BP

Storage

DBL Gentamicin Injection BP will usually be stored in the pharmacy or on the hospital ward. It is kept in a cool dry place, protected from light, where the temperature stays below 25C.

Product description

What it looks like

DBL Gentamicin Injection BP is a clear, colourless liquid in glass ampoules. DBL Gentamicin Injection BP 10 mg/1 mL is available in packs of 5 ampoules.

Ingredients

Active ingredients:

- Each 1 mL of DBL Gentamicin Injection BP contains gentamicin sulfate equivalent to 10 mg.

Other ingredients:

- disodium edetate
- water for injections
- sulfuric acid
- sodium hydroxide.

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

Sponsor

DBL Gentamicin Injection BP is supplied in Australia by:

Pfizer Australia Pty Ltd

Sydney NSW.

Toll Free Number: 1800 675 229.

www.pfizermedicalinformation.com.au

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