Gentamicin Injection BP

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> 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 Gentamicin Injection BP?

Gentamicin Injection BP contains the active ingredient gentamicin sulfate. Gentamicin Injection BP is used to treat bacterial infections.

For more information, see Section 1. Why am I being treated with Gentamicin Injection BP? in the full CMI.

2. What should I know before treatment with Gentamicin Injection BP?

You should not be given Gentamicin Injection BP if you have ever had an allergic reaction to gentamicin or any of the ingredients listed at the end of the CMI, or if you have experienced previous toxic reactions (hearing loss, kidney damage) to an antibiotic.

Talk to your doctor if you have: kidney problems, hearing problems, neuromuscular disorders, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section <u>2. What should I know before treatment with Gentamicin Injection BP?</u> in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Gentamicin Injection BP 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 is Gentamicin Injection BP given?

Gentamicin Injection BP is given as an injection into a muscle or as a slow injection (drip) into a vein.

More instructions can be found in Section <u>4. How is</u> <u>Gentamicin Injection BP given?</u> in the full CMI.

5. What should I know during treatment with Gentamicin Injection BP?

Things you should do

 Tell your doctor straight away if: the symptoms of your infection do not improve within

	a few days, or if they become worse; you have stomach cramps, diarrhoea; have dizziness, vertigo, tinnitus, roaring in the ears or hearing loss. Remind any doctor, nurse, dentist or pharmacist who are treating you that you are being given Gentamicin Injection BP.
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.
Driving or using machines	 Gentamicin Injection BP may cause dizziness or vertigo in some people. Do not drive, operate machinery or do anything else that could be dangerous until you know how Gentamicin Injection BP affects you.
Looking after your medicine	 Gentamicin Injection BP is stored in the pharmacy or on the

hospital ward under the		
correct conditions.		

For more information, see Section <u>5. What should I know</u> <u>during treatment with Gentamicin Injection BP?</u> in the full CMI.

6. Are there any side effects?

Side effects of this medicine may include loss of appetite, weight loss; numbness, skin tingling; skin rash/itching/reddening; vomiting, nausea; increased saliva; sore mouth; muscle/joint pain; pain at injection site; increased temperature; confusion, hallucinations; mental depression; headache; visual disorders; hair loss; kidney problems; shallow breathing, shortness of breath, swelling of throat; diarrhoea; convulsions; dizziness, vertigo, balance problems tinnitus, roaring in ears/hearing loss.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

Gentamicin Injection BP

Active ingredient: gentamicin sulfate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Gentamicin Injection BP. 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 Gentamicin Injection BP.

Where to find information in this leaflet:

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

1. Why am I being treated with Gentamicin Injection BP?

Gentamicin Injection BP contains the active ingredient gentamicin sulfate. It is an antibiotic that belongs to a group of medicines called aminoglycoside antibiotics.

Gentamicin Injection BP is used to treat the bacterial infections in the following areas of the body: bloodstream, lung, urine, skin, bone, liver, stomach, spleen, gallbladder, intestines; and also septic abortion (miscarriage) and burns complicated by the infection.

Gentamicin Injection BP works by stopping protein production in susceptible bacteria which leads to their death.

2. What should I know before treatment with Gentamicin Injection BP?

Warnings

Do not use Gentamicin Injection BP if:

- you are allergic to gentamicin, or any of the ingredients listed at the end of this leaflet.
- you have experienced previous toxic reactions including hearing loss, often with loss of balance or damage to your kidneys to an antibiotic.

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 problems with your kidneys
- have neuromuscular disorders, such as: myasthenia gravis, parkinsonism (a disorder affecting movement with trembling, rigid posture, slow movements and/or a shuffling, unbalanced walk)
- are significantly overweight
- have diarrhoea following antibiotic use

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>. Are there any side effects?

Tell your doctor if you are pregnant or intend to become pregnant

Gentamicin Injection BP is potentially harmful to the fetus. Like most aminoglycoside antibiotics, Gentamicin Injection BP is not recommended for use during pregnancy. If there is a need for you to be given Gentamicin Injection BP, your doctor will discuss

with you the benefits and risks of using it during your pregnancy.

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

Gentamicin Injection BP passes into breast milk and is not recommended for use during breastfeeding. If there is a need for you to be given Gentamicin Injection BP, your doctor will discuss with you the benefits and risks of being given Gentamicin Injection BP whilst you are breast-feeding.

If you have not told your doctor about any of the above, tell them before you are given Gentamicin Injection BP.

Use in the elderly

There may be a greater chance of loss of hearing if you are over 65 years of age.

Use in children

Gentamicin Injection BP should be used with caution in premature and newborn babies.

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 Gentamicin Injection BP, these include:

- Digoxin, a medicine used to treat heart problems
- some medicines used during surgery, such as suxamethonium, some anaesthetics, large transfusions with citrated anticoagulated blood
- opioid analgesics, medicine used for strong pain relief
- some other anti-infective medicines, such as aminoglycosides, polymyxin B, colistin, vancomycin, amphotericin B, clindamycin, cephalosporins, ciclosporins, penicillins
- cisplatin, a medicine used in cancer treatment
- some diuretics, medicines used to treat swelling of the ankles, feet or legs, such as etacrynic acid, furosemide
- indometacin, a medicine used to treat arthritis and inflammation
- neostigmine, a medicine used to relax muscles
- Vitamin K

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Gentamicin Injection BP.

4. How is Gentamicin Injection BP given?

How much is given

 Your doctor will decide how much Gentamicin Injection BP you should receive and the length of time for which you should receive it.

How is Gentamicin Injection BP given

 Gentamicin Injection BP is given as an injection into a muscle or as a slow injection (drip) into a vein.

If you are given too much Gentamicin Injection BP

As Gentamicin Injection BP 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 or nurse immediately.

5. What should I know during treatment with Gentamicin Injection BP?

Things you should do

Tell your doctor straight away if you:

 the symptoms of your infection do not improve within a few days, or if they become worse

- have stomach cramps or diarrhoea
- have dizziness, vertigo, tinnitus, roaring in the ears or hearing loss

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

Remind any doctor, dentist or pharmacist who are treating you that you are using Gentamicin Injection BP.

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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Gentamicin Injection BP affects you.

Gentamicin Injection BP may cause dizziness and vertigo in some people

Drinking alcohol

No information is available.

Looking after your medicine

Gentamicin Injection BP is stored in the pharmacy or on the hospital ward under the correct conditions.

Disposal of Gentamicin Injection BP

The hospital staff will dispose of any leftover Gentamicin Injection BP.

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.

side effects

side effects	What to do
 loss of appetite, weight loss numbness, skin tingling skin rash and itching, skin reddening vomiting, nausea increased saliva sore mouth muscle and joint pain pain at injection site increased temperature 	Speak to your doctor if you have any of these side effects and they worry you.

side effects	What to do
 confusion, hallucinations, mental depression 	
• headache	
visual disorders	
changes in blood pressure	
hair loss or thinning	

Serious side effects

Serious side effects	What to do
 kidney problems shallow breathing, shortness of breath, swelling of the throat diarrhoea dizziness, vertigo convulsions (fits or seizures) tinnitus, roaring in the ears and hearing loss, balance problem 	Alert your nurse and/or doctor straight away if you notice any of these serious side effects.

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.

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 Gentamicin Injection BP contains

Active ingredient	Gentamicin sulfate
(main ingredient)	
Other ingredients	Disodium edetate

(inactive ingredients)	Water for injections
	Sodium hydroxide
	Sulfuric acid

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

Each Gentamicin Injection BP contains Gentamicin (as Sulfate) 80 mg/2 mL.

What Gentamicin Injection BP looks like

Gentamicin Injection BP is clear, colorless solution in an ampoule.

Aust R 11376

Who distributes Gentamicin Injection BP

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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