

SCHEDULING STATUS**S4****Gentamicin 1 mg/mL Solution for Infusion B Braun****Gentamicin 3 mg/mL Solution for Infusion B Braun**

Gentamicin sulphate

Read all of this leaflet carefully before you start taking Gentamicin Solution for Infusion B**Braun**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- **Gentamicin Solution for Infusion B Braun** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.
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What is in this leaflet:

1. What Gentamicin Solution for Infusion B Braun is and what it is used for
2. What you need to know before you use Gentamicin Solution for Infusion B Braun
3. How to use Gentamicin Solution for Infusion B Braun
4. Possible side effects
5. How to store Gentamicin Solution for Infusion B Braun
6. Contents of the pack and other information

1. What Gentamicin Solution for Infusion B Braun is and what it is used for

Gentamicin Solution for Infusion B Braun belongs to a group of antibiotics called aminoglycosides. They are used to treat severe infections with bacteria that can be killed by the active substance gentamicin.

Gentamicin Solution for Infusion B Braun should, only be used when less toxic antimicrobial medicines are not effective.

You may receive Gentamicin Solution for Infusion B Braun to treat the following diseases:

- Acute and recurrent infections of kidneys, urinary ducts and bladder
- Severe systemic infection, e.g. Sepsis, peritonitis (a redness and swelling of the lining of your belly or abdomen, meningitis (swelling of the protective membranes covering the brain and spinal cord
- Bone and soft tissue infections, infected burns
- Hospital acquired infections of parts of the body involved in breathing, such as the sinuses, throat, airways or lungs.

Gentamicin Solution for Infusion B Braun should, for all indications except complicated urinary tract infections, only be used in combination with other antibiotics for the treatment of the diseases listed above.

2. What you need to know before you take Gentamicin Solution for Infusion B Braun

Do not take Gentamicin Solution for Infusion B Braun:

- if you have shown signs of hypersensitivity (severe allergy) to gentamicin or any other ingredients listed in “what Gentamicin Solution for Infusion B Braun contains” on previous occasions
- if you suffer from a disorder called myasthenia gravis (severe weakness of selected muscles of the body).

Take special care with Gentamicin Solution for Infusion B Braun:

- if you are pregnant or breast-feeding
- if you are an elderly patient
- if your kidneys are not working properly

- if you have an ear, hearing or balance disorder, a history of ear infections or if you have been treated with medicines that affect hearing in the past
- if you experience muscle weakness or if you have any disease affecting the function of your muscles such as Parkinson's disease
- if you know (or think you have) a mitochondrial disease (mutations in the parts of your cells which help make energy); certain mitochondrial diseases may increase your risk of hearing loss with this product.

If any of these apply to you, you will receive gentamicin only if your doctor considers it essential for the treatment of your disease. Your doctor will take special care to adjust your gentamicin dose properly.

You should inform your doctor immediately if you experience severe diarrhoea.

Your infection might not respond to gentamicin if it did not respond to other aminoglycoside antibiotics.

You may show an allergic reaction to gentamicin if you are already allergic to another aminoglycoside antibiotic.

In order to reduce the risk of damage to your ear nerve and your kidneys your doctor will carefully consider the following:

- They will monitor your hearing, balance, and renal function before, during and after treatment.
- Dosage will be adapted strictly according to your kidney function.
- If you have impaired kidney function, the total dosage will also take into account antibiotics administered to the site of infection.
- Blood concentrations of gentamicin need to be measured during therapy depending on your individual situation.

- If you already have ear nerve damage (hearing or balance function impairment), or where treatment is long-term, your doctor will carry out additional monitoring of the balance function and hearing.
- If possible, you will receive the therapy with gentamicin for not longer than 7-10 days (a longer duration of treatment may be necessary in difficult and complicated infections).
- There should be sufficient time, 7 – 14 days, between individual treatments with gentamicin or other closely related antibiotics.
- Avoiding administration of other substances with possibly damaging effects on the ear nerve or the kidneys together with gentamicin. If this is unavoidable, particular careful monitoring of your kidney function is necessary.
- Your body fluid level and urine production should be in the normal range.

This medicine contains 283 mg sodium (main component of cooking/table salt) in each 80 mL bottle solution for infusion. This is equivalent to 14,1 % of the recommended maximum daily dietary intake of sodium for an adult

Only for 3mg/mL

This medicine contains 425 mg sodium (main component of cooking/table salt) in each 120 mL bottle solution for infusion. This is equivalent to 21,3 % of the recommended maximum daily dietary intake for sodium for an adult

Taking other medicines with Gentamicin Solution for Infusion B Braun:

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines). See Do not take **Gentamicin Solution for Infusion B Braun**.

Tell your doctor if you are taking or using any of the following medicines:

- antibiotics that also affect your kidneys or hearing such as other aminoglycosides, cephalosporins, (notably cephalothin) and methicillin medicines used to thin the blood, such as warfarin and phenindione

- amphotericin B (medicine used to treat fungal infections)
- cyclosporin (a medicine that reduces the activity of the body's immune system)
- cisplatin (anti-cancer medicine)
- some diuretics (water tablets), such as ethacrynic acid and furosemide
- muscle relaxants used during general anaesthesia (such as tubocurarine and succinylcholine)

Pregnancy, breastfeeding and fertility

Gentamicin Solution for Infusion B Braun should not be administered during pregnancy

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before allowing this medicine to be administered.

Driving and using machines

Do not drive if you experience any effect after receiving Gentamicin Solution for Infusion B Braun which may impair your ability to drive or use machines.

3. How to use Gentamicin Solution for Infusion B Braun

Gentamicin Solution for Infusion B Braun will be given to you by your doctor or nurse. The doctor or nurse will administer the correct dose. If you have the impression that the effect of Gentamicin Solution for Infusion B Braun is too strong or too weak, talk to your doctor or pharmacist.

Your doctor will tell you how long your treatment with Gentamicin Solution for Infusion B Braun will last.

The dose of medicine given to you will depend on how serious the infection is, your age, body weight and how well your kidneys are working.

As this medicine will be given to you whilst you are in hospital it is unlikely that you will be given too little or too much, however tell you doctor or pharmacist if you have any concerns.

The amount of gentamicin in your blood will be measured regularly to check that the correct blood levels have been achieved. Treatment with gentamicin may cause damage to hearing and also to kidney function.

Your doctor will decide, depending on your condition, how long you should receive gentamicin. In some cases, your doctor may carry out blood tests to check your kidney function before and during treatment with gentamicin. Occasionally you may also be asked to take a hearing test to check the drug is not affecting your hearing.

If you are given more Gentamicin Solution for Infusion B Braun than you should

Signs and Symptoms

At first, the treatment will be stopped, there is no specific antidote. If it does happen, the doctor will treat any symptoms that follow. Symptoms of overdose include feelings of dizziness or a “spinning sensation” and hearing loss. Inform your doctor or nurse if you experience these side effects soon after being given Gentamicin Injection.

Gentamicin can be removed from the blood by kidney dialysis.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Gentamicin Solution for Infusion B Braun can have side effects.

Not all side effects reported for Gentamicin Solution for Infusion B Braun are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Gentamicin Solution for Infusion B Braun, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, the medical practitioner will stop administering Gentamicin Solution for Infusion B Braun. If some effects happen afterwards tell your doctor immediately or go to the casualty department at your nearest hospital:

- Severe acute hypersensitivity (allergic) reactions and anaphylactic shock: Skin rash, itching and difficulty in breathing can be signs of acute hypersensitivity.
- Acute Kidney failure: Decreased amount of urine or complete urination stop (oliguria, anuria), excessive urination at night, and generalized swelling (fluid retention) are signs of acute kidney failure.
- Serious allergic reaction of the skin, mouth and throat with blistering and redness of the skin (erythema multiforme) which in severe cases can affect the internal organs (Stevens-Johnson syndrome, toxic epidermal necrolysis), skin detachment (toxic epidermal necrolysis, or Lyell's syndrome).
- Disorders of the brain and nerves: Swelling of the brain (encephalopathy), muscle paralysis (neuromuscular block), seizures, and impaired kidney function.
- Ear or nerve disorder: Hearing or balance problems

These are all very serious side effects. If you have them, you may have had a serious reaction to Gentamicin Solution for Infusion B Braun. You may need urgent medical attention or hospitalisation.

Less frequent side effects:

- Impaired blood clotting
- More or less intense skin redness without papules or blisters
- Low blood levels of potassium, calcium and magnesium
- Disorder of the kidneys
- Loss of appetite
- Weight loss
- Disorder of the nerves
- Abnormal sensory perception
- Vomiting, nausea
- Increased liver enzymes and urea in the blood (all reversible)
- Increased salivation
- Inflammation of the mouth lining

- Skin reddening
- Muscle pain
- Infection with gentamicin-resistant germs
- Very severe inflammation of the large intestine
- Blood disorders affecting certain blood components and generally detected by blood tests
- Anaemia
- Confusion, hallucinations, depression
- Dizziness, vertigo, balance disorders, headache
- Visual disturbances
- Loss of hearing
- Inner ear problems, ringing in the ear
- Changes in blood pressure
- Hair loss
- Muscle tremor
- Abnormal changes to urine (so called Fanconi-like syndrome, associated with high doses given over a long time)
- Pain at the injection site.
- Irreversible loss of hearing, deafness. Symptoms which may be sign of hearing damage include: temporary loss of hearing, ringing in the ears, dizziness, and balance and visual disruptions.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects via

https://www.sahpra.org.za/documents/86422f1b6.04_ARF1_Jul16_v4.pdf. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Gentamicin Solution for Infusion B Braun**STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**

Store at or below 25 °C.

Keep in original packaging until required for use.

Do not use after the expiry date stated on the label.

The solution should be used immediately.

This medicinal product is for single use only.

Any unused solution should be discarded.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information**What Gentamicin Solution for Infusion B Braun contains****Gentamicin 1 mg/mL Solution for Infusion B Braun**

1 mL of solution for infusion contains gentamicin sulphate equivalent to
1 mg gentamicin.

The other ingredients are:

Sodium chloride, water for injection

Gentamicin 3 mg/mL Solution for Infusion B Braun

1 mL of solution for infusion contains gentamicin sulphate equivalent to
3 mg gentamicin.

The other ingredients are:

Disodium edetate, sodium chloride, water for injection

What Gentamicin Solution for Infusion B Braun looks like and contents of the pack**Gentamicin 1 mg/mL Solution for Infusion B Braun**

10/20 x 80 mL are packed in low density polyethylene containers. The container is already hermetically closed before the closure system is applied. Additional closure cap on top of the sealed polyethylene containers is made of polyethylene. Between the polyethylene container and closure cap exists an elastomeric disk.

Gentamicin B.Braun 3 mg/mL solution for infusion

10/20 x 80 mL or 10/20 x 120 mL are packed in low density polyethylene containers. The container is already hermetically closed before the closure system is applied. Additional closure cap on top of the sealed polyethylene containers is made of polyethylene. Between the polyethylene container and closure cap exists an elastomeric disk.

Not all packs or pack sizes are necessarily marketed

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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