



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

GENTAMYCIN INJECTION

Gentamycin Injection BP 80mg/2ml

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again before, during or after use of this medicine.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please inform your health care provider.

In this leaflet:

1. What Gentamycin Injection is and what it is used for
2. What you need to know before you are given Gentamycin injection
3. How to take Gentamycin Injection
4. Possible side effects
5. How to store Gentamycin Injection
6. Contents of the pack and other information

1. WHAT GENTAMYCIN INJECTION IS AND WHAT IT IS USED FOR

Gentamycin Injection contains the active substance Gentamycin. It belongs to a group of antibiotics called aminoglycosides. This medicine is used to treat severe infections caused by bacteria. This includes:

- infections of the urinary tract (including kidneys or bladder)
- infections in the chest (including lungs), such as hospital-acquired and ventilator-associated pneumonia (HAP and VAP).
- bacterial inflammation of the heart lining (endocarditis).
- infections of the abdomen.
- infections of the brain and spinal cord (meningitis caused by bacteria)
- infections of the bones and joints (osteomyelitis and bacterial arthritis)
- management of neutropenic patients with fever that is suspected to be due to a bacterial infection
- infections of the whole body due to the presence of *Listeria monocytogenes* in the blood
- severe infection in newborn babies
- infections of the blood (bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above)

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN GENTAMYCIN INJECTION

You must not be given Gentamycin Injection

- if you are allergic to Gentamycin or any of the other ingredients of this medicine.
- subcutaneously (beneath the skin), as it is not effective via this route and necrosis (death of body tissue) may occur at the injection site



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Warnings and precautions: Talk to your doctor, pharmacist, or nurse before you are given Gentamycin:

- if you have problems with your kidneys
- if you have liver problems
- if you have diabetes
- if you suffer from deafness or have a hearing or balance disorder, a history of ear infections or if you have been treated with medicines that affect hearing in the past. In these cases, you will be given Gentamycin only if your doctor regards this treatment as essential to treat your illness. Your doctor will take special care to adjust your Gentamycin injection dose. Your doctor will be particularly vigilant if you have a disease affecting your nerve and muscle functions, such as Parkinson's disease or myasthenia gravis, or if you are given a muscle relaxant during surgery, because Gentamycin may have a blocking effect on your nerve and muscle functions.

Taking other medicines with Gentamycin Injection

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Medicines that may damage the kidneys and hearing.

Tell your doctor if you are receiving or about to receive treatment with medicines that may potentially damage the kidneys or hearing, as there is an increased risk of side effects. These medicines include:

- Amphotericin B (used to treat fungal infections)
- Polymyxin B (antibiotic)
- Ciclosporin (used in organ transplants or for severe skin problems)
- Cisplatin and other organoplatinum compounds (used to treat cancer)
- Other antibiotics of aminoglycoside group, such as tobramycin, streptomycin
- Water tablets or injections (diuretics), such as furosemide
- Tacrolimus (used after organ transplants)
- Cephalothin (antibiotic of cephalosporins group)
- Methoxyflurane (an anaesthetic gas)
- Indomethacin (one of a group of medicines called nonsteroidal anti-inflammatory agents, used to treat pain and inflammations)
- Anticoagulants (used to thin the blood), such as warfarin and phenindione
- Biphosphonates (used to treat osteoporosis)
- Iodinated contrast media (agent used to facilitate radiographic imaging), antiviral agents (such as the ciclovir group, foscarnet), methotrexate, pentamidine
- Antibiotics of the glycopeptide group, such as vancomycin and teicoplanin
- Neostigmine or pyridostigmine (used to treat muscle weakness)
- Digoxin (used to treat various heart conditions)

Medicines whose effect may be increased by Gentamycin Injection

Also tell your doctor if you are taking the following medicines, as their effect may be increased when used together with Gentamycin:

- Botulinum toxin (used to lower the activity of overactive muscles)



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- Curare medicines (muscle relaxants)

Pregnancy and Breast-feeding

Pregnancy

Gentamycin should only be used during pregnancy for life-threatening indications and when no safer treatment alternatives are available due to the potential danger for the unborn baby. This medicine is not recommended for use in pregnancy unless considered appropriate by your doctor.

Breast-feeding

Do not breast-feed during your treatment with Gentamycin. Small amounts of Gentamycin are excreted in human milk and low concentrations have been found in the serum of breastfed infants. A decision must be made whether to stop breastfeeding or whether to discontinue or not to give Gentamycin. The breast-fed infant may suffer from diarrhea and thrush in the mouth (fungal infection) whilst the mother is being treated with this medicine

Driving and using machines

Do not drive or operate machinery as Gentamycin may reduce mental alertness.

3. HOW TO TAKE GENTAMYCIN INJECTION

Your doctor will decide how much to give you, depending on your weight. The correct dose also depends on the type of infection and any other illnesses you may have. Blood samples will be taken by your doctor or nurse to check the dose is right for you. The amount of Gentamycin in your blood will be measured regularly to check that the correct blood levels have been achieved. Treatment with Gentamycin may cause damage to hearing and also to kidney function. Your doctor will decide, depending on your condition, how long you should receive Gentamycin. In some cases, your doctor may carry out blood tests to check your kidney function before and during treatment with Gentamycin. Occasionally you may also be asked to take a hearing test to check the medicine is not affecting your hearing.

Dosage

The recommended daily dose for children, adolescents and adults with normal kidney function is 3 to 6 mg / kg body weight per day and should preferably be given as a single dose, or else divided into 2 separate doses.

Use in infants

- The daily dose recommended in children aged 1 year and above with normal renal function, is 3 – 6 mg / kg / day as one single dose (preferred) or two divided doses.
- The recommended daily dose for infants after the first month of life is 4.5 – 7.5 mg / kg body weight per day and should be preferably given as a single dose, or else divided into 2 separate doses.
- The recommended daily dose for newborn infants is 4 – 7 mg / kg body weight per day. Due to the longer half-life, newborn infants are given the required dose as a single dose.



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Use in patients with kidney problems

If you have kidney problems your daily recommended dose should be reduced and adjusted to kidney function.

Method of administration

This medicine is injected into a muscle (intramuscularly) or into a vein (intravenously) after dilution.

Duration of use

The duration of use is decided by your doctor. For common bacterial infectious diseases, the duration of treatment depends on the progression of the disease. Normally, a treatment period of 7 to 14 days is sufficient. The duration of therapy should preferably not exceed 10 to 14 days. A course of treatment with Gentamycin immediately after a previous course of aminoglycoside treatment should be avoided. You should wait 7 to 14 days before starting treatment with Gentamycin. Please talk to your doctor if you have the impression that the effect of Gentamycin is too strong or too weak.

If you miss a dose of Gentamycin Injection

Your doctor has instructions about when to give you your medicine. It is most unlikely that you will not be given the medicine as it has been prescribed. If you think that you may have missed a dose, then talk to your doctor.

If you receive more Gentamycin Injection than you should

It is unlikely that your doctor will give you too much medicine. Your doctor will monitor your progress and check the medicine you are given. Always ask your doctor if you are not sure why you are getting a dose of medicine.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. Tell your doctor straight away if you notice any signs of an allergic reaction, including anaphylactic shock (life threatening allergic reaction), such as:

- itching or skin rashes
- swelling of the face, lips or throat
- difficulty in breathing or wheeziness

Other possible side effects

Common: may affect up to 1 in 10 people

- problems with kidney function

Uncommon: may affect up to 1 in 100 people

- problems with blood clotting
- intense skin redness without papules or blisters

Rare: may affect up to 1 in 1,000 people

- low blood levels of potassium, calcium and magnesium



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- increased levels of aldosterone in the blood
- loss of appetite
- weight loss
- damage of peripheral nerves
- loss of feeling
- feeling or being sick
- increased liver enzymes and urea in the blood (all reversible)
- increased production of saliva
- inflammation of the mouth lining
- skin reddening
- muscle pain
- increased body temperature
- increased serum bilirubin level in the blood

Very rare: may affect up to 1 in 10,000 people

- superinfection (with Gentamycin-resistant germs)
- very severe inflammation of the colon
- blood disorders affecting certain blood components and generally detected by blood tests
- decrease in the number of phosphates in the blood
- confusion, hallucinations, depression
- a collection of brain problems
- seizures (fits)
- neuromuscular block
- dizziness, vertigo, balance disorders, headache
- visual disturbances
- loss of hearing
- inner ear problems, tinnitus
- low blood pressure
- high blood pressure
- serious allergic reaction of the skin and mucous membranes with blistering and redness of the skin (erythema multiforme) which can, in very severe cases, affect the internal organs and become life-threatening (Steven-Johnson's Syndrome, toxic epidermal necrolysis), skin detachment (Toxic epidermal necrolysis, or Lyell's syndrome)
- hair loss
- muscle wasting (decrease in the mass of the muscle)
- acute kidney failure, raised phosphate levels in the urine and amino acids (known as fanconi syndrome, associated with high doses administered over a long period of time)
- pain at the injection site.

Reporting of side effects

If you get any side effects, talk to your healthcare provider. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.



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5. HOW TO STORE GENTAMYCIN INJECTION

- Keep all medicines out of the reach of children.
- Store below 30°C.
- Do not use this medicine after the expiry date 'Exp. Date' which is stated on the label. The expiry date refers to the last day of the month.

Do not throw away any medicines via wastewater or household waste. Ask your nurse or pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

What Gentamycin Injection contains

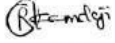


The active substance of Gentamycin Injection is Gentamycin 80mg/2ml.

What Gentamycin Injection looks like and contents of the pack

Gentamycin injection is packed as 10x2ml ampoule injection, placed in a carton with patient information leaflet.

MANUFACTURER

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