

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

GENTAMICIN INJECTION USP
Gentamicin Sulphate

Read this carefully before you start taking **Gentamicin Injection USP** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Gentamicin Injection USP**.

What is Gentamicin Injection USP used for?

Gentamicin Injection USP is used to treat serious bacterial infections such as:

- blood infections
- chest infections
- infections of system that carries urine out of the body (Urinary tract)
- Bone and tissue infections
- Infected wounds or burns

Antibacterial drugs like **Gentamicin Injection USP** treat only bacterial infections. They do not treat viral infections. Although you may feel better early in treatment, **Gentamicin Injection USP** should be used exactly as directed. Misuse or overuse of **Gentamicin Injection USP** could lead to the growth of bacteria that will not be killed by **Gentamicin Injection USP** (resistance). This means that **Gentamicin Injection USP** may not work for you in the future.

How does Gentamicin Injection USP work?

Gentamicin Injection USP is in a class of medications called aminoglycoside antibiotics. It works by preventing bacteria from growing and by killing them.

What are the ingredients in Gentamicin Injection USP?

Gentamicin Injection USP 10 mg per mL and 40 mg per mL contain:

Medicinal ingredient: Gentamicin as gentamicin sulphate.

Non-medicinal ingredients: disodium edetate dihydrate, sodium bisulfite, sulfuric acid, sodium hydroxide, and water for injection. Gentamicin Injection USP 40 mg per mL also contains: methylparaben and propylparaben

Gentamicin Injection USP comes in the following dosage forms:

Gentamicin Injection USP comes a sterile solution (liquid) containing 10 mg per mL or 40 mg per mL of gentamicin as gentamicin sulphate.

Do not use Gentamicin Injection USP if you have an allergy to:

- to gentamicin
- other aminoglycosides antibiotics such as amikacin, kanamycin, parmomycin, streptomycin, tobramycin
- any of the other ingredients in **Gentamicin Injection USP** (see What are the ingredients in Gentamicin Injection USP?)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Gentamicin Injection USP. Talk about any health conditions or problems

you may have, including if you:

- have a history of kidney problems and/or diabetes
- have a history of hearing problems or if you have been treated with medicines that affect hearing in the past (see “The following may interact with **Gentamicin Injection USP**” section)
- have problems with balance
- have a history of muscles problems such as myasthenia gravis or Parkinson’s disease.
- are pregnant or planning to become pregnant
- are breastfeeding or planning to breastfeed

Other warnings you should know about:

Gentamicin Injection USP may harm your hearing or your kidneys (see “**Serious Side Effects and What to do About Them**” section). While you are using **Gentamicin Injection USP**, your healthcare professional may do bloodwork to check how your kidneys are working. Sometimes you may also take a hearing test to check if **Gentamicin Injection USP** is not affecting your hearing.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Gentamicin Injection USP:

- Medications that affect your kidneys or hearing such as:
 - Other antibiotics;
 - aminoglycosides (e.g. amikacin, kanamycin, parmomycin, streptomycin tobramycin)
 - cephalosporins such as cefazolin, cefixime or cephalexin
 - clindamycin
 - carbenicillin, piperacillin, polymixin B, colistin
 - vancomycin
 - Amphotericin B, a medicine used to treat fungal infections
 - Anti-cancer drugs, such as cisplatin and carboplatin
 - Diuretics, “water pills” such as ethacrynic acid or furosemide
 - Medicines used to suppress the immune system, such as cyclosporine and tacrolimus
 - Medications used to reduce fever and inflammation (nonsteroidal anti-inflammatory) such as indomethacin
 - Zalcitabine, an HIV medication
 - Mannitol
- Medications given during surgery to relax the muscles such as tubocurarine and succinylcholine
- Medicines used to treat myasthenia gravis such as neostigmine and pyridostigmine.
- Magnesium

Many other medications may also interact with gentamicin. Tell your healthcare professional about all the medications you are taking, even those that do not appear on this list.

How to take Gentamicin Injection USP:

Your healthcare professional will give **Gentamicin Injection USP** as a shot into a muscle or as a slow drip through a needle into a large vein (infusion).

Usual dose:

Your healthcare professional will decide on the dose that is right for you. This will depend on your age, weight, type of infection and how well your kidneys are working.

Your healthcare professional will also tell you how long to use **Gentamicin Injection USP**

Ask your healthcare professional if you have any questions about how many doses of **Gentamicin Injection USP** you will need or when you will receive them.

Overdose:

If you think you have been given too much **Gentamicin Injection USP**, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

Gentamicin Injection USP is administered by a healthcare professional. If you think you have missed a dose talk to your healthcare professional.

What are possible side effects from using Gentamicin Injection USP?

These are not all the possible side effects you may feel when taking **Gentamicin Injection USP**. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- nausea, vomiting
- decreased appetite
- weight loss
- weakness or tiredness
- increased salivation
- rash (area of itchy, red, irritated or swollen skin)
- hives (red and sometimes itchy bumps on your skin)
- headache
- pain at injection site
- joint pain
- fever

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON Kidney Problems: dark-coloured urine, increased/decreased urination, unusual tiredness or weakness, nausea, vomiting, swelling of the arms or legs			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Hearing Problems: dizziness, hearing loss, ringing in the ears, problems with balance, sensation of spinning			✓
UNKNOWN FREQUENCY Nervous System Problems: trouble walking, dizziness, numbness, skin tingling, muscle twitching, seizure (fits), trouble breathing			✓
Serious Allergic Reaction (hypersensitivity): swelling of the face, lips, tongue or throat, trouble breathing or swallowing, itching, hives, skin rash with or without blisters or peeling			✓
Decreased of cells in the blood that help the blood clot (Platelets): •easy bruising, •abnormal bleeding, bleeding when you brush your teeth, •Pinpoint red spots on the skin		✓	
Decreased White Blood Cells: (usually found when your doctor orders tests) more likely to develop infections, fatigue, fever, aches, pains and flu-like symptoms		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>
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Storage:

Gentamicin Injection USP vials should be protected from light and stored at room temperature (15 – 30 °C).

Keep out of reach and sight of children.

If you want more information about Gentamicin Injection USP:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website www.sandoz.ca, or by calling 1-800-361-3062.

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