

GENTAMICIN NORIDEM*

Consumer Medicine Information (CMI) summary

The [full CMI](#) 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 using GENTAMICIN NORIDEM?

GENTAMICIN NORIDEM contains the active ingredient Gentamicin sulfate. GENTAMICIN NORIDEM is used to treat serious bacterial infections.

For more information, see Section [1. Why am I using GENTAMICIN NORIDEM?](#) in the full CMI.

2. WHAT SHOULD I KNOW BEFORE I USE GENTAMICIN NORIDEM

Do not use if you have ever had an allergic reaction to GENTAMICIN NORIDEM or other aminoglycoside antibiotics such as amikacin, tobramycin or neomycin or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use GENTAMICIN NORIDEM?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with GENTAMICIN NORIDEM 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 DO I USE GENTAMICIN NORIDEM?

Gentamicin is given as an injection into a muscle or as a slow injection into a vein (intravenously). This medicine should only be given by a doctor, nurse or other trained person

More instructions can be found in Section [4. How do I use GENTAMICIN NORIDEM?](#) in the full CMI.

5. WHAT SHOULD I KNOW WHILE USING GENTAMICIN NORIDEM?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using GENTAMICIN NORIDEM.Tell your doctor or pharmacist if you think you may be pregnant
Things you should not do	<ul style="list-style-type: none">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.Gentamicin should not be taken while you are pregnant
Looking after your medicine	<ul style="list-style-type: none">GENTAMICIN NORIDEM will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using GENTAMICIN NORIDEM?](#) in the full CMI.

6. Are there any side effects?

Some common side effects are pain at the injection site, nausea or vomiting, headache. More serious side effects that may occur include allergic reaction characterized by swelling of limbs, face, lips, mouth or throat, shortness of breath or breathing difficulties, rash, itching or severe skin reaction. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

GENTAMICIN NORIDEM *

Active ingredient(s): Gentamicin sulfate

Consumer Medicine Information (CMI)

This leaflet provides important information about using GENTAMICIN NORIDEM. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using GENTAMICIN NORIDEM.**

Where to find information in this leaflet:

- [1. Why am I using GENTAMICIN NORIDEM?](#)
- [2. What should I know before I use GENTAMICIN NORIDEM?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use GENTAMICIN NORIDEM?](#)
- [5. What should I know while using GENTAMICIN NORIDEM?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using GENTAMICIN NORIDEM?

GENTAMICIN NORIDEM contains the active ingredient **Gentamicin sulfate**. GENTAMICIN NORIDEM is an antibiotic that belongs to a group of medicines called aminoglycosides (pronounced a-my-noe-GLY-koe-sides).

GENTAMICIN NORIDEM is used to treat serious bacterial infections. Gentamicin works by killing bacteria or preventing their growth. It is used for the treatment of serious infections, including:

- **septicaemia (infection of the blood)**
- **respiratory tract infections**
- **infected wounds**
- **bone or tissue infections**
- **infected burns**
- **urinary tract infections.**

Your doctor may have prescribed gentamicin for another reason.

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

This medicine is available only with a doctor's prescription

2. WHAT SHOULD I KNOW BEFORE I USE GENTAMICIN NORIDEM?

Warnings

Do not use GENTAMICIN NORIDEM if:

if you have an allergy to gentamicin or other aminoglycoside antibiotics such as

- Amikacin
- Tobramycin
- Neomycin
- or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

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

Check with your doctor if you:

have any medical conditions especially the following:-

- kidney problems
- muscular disorders (eg myasthenia gravis, Parkinson's disease)
- hearing problems.

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 [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Like most aminoglycoside antibiotics, gentamicin is not recommended for use during pregnancy. If there is a need for you to be given gentamicin, your doctor or pharmacist will discuss with you the benefits and risks of using it during your pregnancy.

Gentamicin may affect your developing baby if you take it during pregnancy. If it is necessary for you to be given Gentamicin Injection, your doctor will discuss with you the benefits and risks of using it during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

If there is a need for you to be given gentamicin, your doctor or pharmacist will discuss the possible risks and benefits of using it during breastfeeding.

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 NORIDEM and affect how it works.

These include:

- fluid tablets (eg frusemide, ethacrynic acid, bumetanide)
- cisplatin, a medicine used to treat cancer
- antibiotics to treat infection such as colistin, vancomycin, clindamycin, cephalosporins and penicillins
- amphotericin, an antifungal medicine
- anaesthetics (eg halothane)
- muscle relaxants (eg succinylcholine).

These medicines may be affected by gentamicin, or may affect how well it works. You may need different amounts of your medicine, or you may need to take/use different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while receiving gentamicin

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 NORIDEM.

3. How do I use GENTAMICIN NORIDEM ?

How much to take / use

- Gentamicin is given as an injection into a muscle or as a slow injection into a vein (intravenously). This medicine should only be given by a doctor, nurse or other trained person.
- Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight and kidney function

If you forget to use GENTAMICIN NORIDEM

As GENTAMICIN NORIDEM is usually given to you in hospital under the supervision of your doctor, it is very unlikely that you will be in a situation where a dose is forgotten.

If you use too much GENTAMICIN NORIDEM

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

If you think that you have used too much GENTAMICIN NORIDEM, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

4. What should I know while using GENTAMICIN NORIDEM?

Things you should do

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

Call your doctor straight away if you notice any of the following:

- swelling of the limbs, face, lips, mouth or throat
- shortness of breath or breathing difficulties
- rash, itching, hives or severe skin reaction

These symptoms are signs of an allergic reaction to gentamicin.

If any of these symptoms happen, tell your doctor or nurse immediately

Remind any doctor, dentist or pharmacist you visit that you are using GENTAMICIN NORIDEM.

Things you should 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.

Looking after your medicine

GENTAMICIN NORIDEM will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

5. 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.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal/Digestive <ul style="list-style-type: none">• Nausea and vomiting	Speak to your doctor if you

<ul style="list-style-type: none"> decreased appetite Neurological <ul style="list-style-type: none"> confusion, depression tiredness or weakness headache Mouth <ul style="list-style-type: none"> increased salivation sore mouth and gums Hair <ul style="list-style-type: none"> Hair loss Muscles & Joints <ul style="list-style-type: none"> Joint pain General body <ul style="list-style-type: none"> fever bruising weight loss Injection Site <ul style="list-style-type: none"> pain at injection site 	have any of these less serious side effects and they worry you.
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Serious side effects

Serious side effects	What to do
Genito-urinary tract <ul style="list-style-type: none"> Decreased urination Neurological <ul style="list-style-type: none"> severe headache, dizziness problems with your balance Fits -Convulsions numbness Ears <ul style="list-style-type: none"> hearing loss Ringing in the ears Muscles & Joints <ul style="list-style-type: none"> Muscle twitching. Skin <ul style="list-style-type: none"> Skin tingling 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor 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.

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.

6. Product details

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

What GENTAMICIN NORIDEM contains

Active ingredient (main ingredient)	Gentamicin
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> Disodium edetate Sodium metabisulfite Water for injections Sodium Hydroxide Sulfuric acid
Potential allergens	<ul style="list-style-type: none"> Sulfites as sodium metabisulfite

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

GENTAMICIN NORIDEM injection contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

GENTAMICIN NORIDEM does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What GENTAMICIN NORIDEM looks like

GENTAMICIN NORIDEM is a clear, colourless liquid and comes in glass ampoules.

GENTAMICIN NORIDEM is available in the following strength and pack:

80mg/2mL ampoule AUST R 391250

Packs of 50 ampoules

Who distributes GENTAMICIN NORIDEM

InterPharma Pty Ltd.
Suite 103, 39 East Esplanade
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This leaflet was prepared in April 2023.