

Package leaflet: Information for the patient
Genticin® Injectable
gentamicin

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Genticin Injectable is and what it is used for

The name of your medicine is Genticin Injectable.

Genticin Injectable contains the active ingredient gentamicin which belongs to a group of medicines called antibiotics.

Genticin Injectable is used in adults and children to treat bacterial infections such as severe chest infections, urinary tract infections and septicaemia.

2. What you need to know before you are given Genticin Injectable

You should not be given Genticin Injectable:

- if you are **allergic** to gentamicin or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to a similar medicine containing an aminoglycoside antibiotic
- if you suffer from **myasthenia gravis**, a disease causing muscle weakness.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given Genticin Injectable:

- if you have any problems with your kidneys, liver or hearing
- if you have, or have a maternal history of mitochondrial mutation disease (a genetic condition) or loss of hearing due to antibiotic medicines, you are advised to inform your doctor or pharmacist before you take an aminoglycoside; certain mitochondrial mutations may increase your risk of hearing loss with this product. Your doctor may recommend genetic testing before administration of Genticin Injectable
- if you have any infections or a fever
- if you have low blood pressure or low blood volume
- if you are considered to be significantly overweight
- if you have Parkinson's disease or any other disease causing muscle weakness
- if you are pregnant or think you may be pregnant.

If any of these apply to you or if you are not sure, tell your doctor.

Monitoring during treatment

Your doctor may want to send you for blood tests from time to time to check the levels of gentamicin in your blood. This is because your doctor may need to keep a careful eye on you during your treatment to prevent damage to your ears. If you are over 65 years of age or the patient is under 1 year of age, they may also monitor your hearing, your balance and how your kidneys and liver are working.

Other medicines and Gentamicin Injectable

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

This is especially important if you are taking:

- Antibiotics such as penicillin, ticarcillin, clindamycin, lincomycin, cephalosporins, vancomycin or other aminoglycoside antibiotics
- Ciclosporin (used to stop the body rejecting bone marrow or organ transplants)
- Cisplatin and fludarabine (chemotherapy drugs)
- Amphotericin (used to treat fungal infections)
- Furosemide (frusemide), and piretanide (used to treat heart problems)
- Muscle relaxants
- Medicines used to treat myasthenia gravis such as neostigmine and pyridostigmine
- Indomethacin (an anti-inflammatory)
- Oral anticoagulants
- Bisphosphonates (used to treat osteoporosis)
- Botulinum toxin

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you are given this medicine.

Pregnancy

Gentamicin Injectable is not recommended for use in pregnancy unless considered appropriate by your doctor.

Breast-feeding

Use of Gentamicin Injectable whilst breastfeeding is not recommended if you are suffering from kidney problems.

Driving and using machines

This medicine should not affect your ability to drive or use machines.

3. How you will be given Gentamicin Injectable

This medicine will be given to you by a doctor or nurse as an injection into a muscle or vein. It can also be given as a drip (infusion). Your doctor will work out the dose which is suitable for you.

The recommended dose in adults with normal kidney function is 3 - 6 mg/kg of body weight per day as one (preferred) up to two single doses. Your doctor may increase the dose or frequency of doses, based on your condition.

Use in children and adolescents

The recommended dose in children aged 1 year and above and adolescents with normal renal function is 3 - 6 mg/kg of body weight per day as one (preferred) up to two single doses.

Use in infants after the first month of life

The daily dose in infants after the first month of life is 4.5 - 7.5 mg/kg of body weight per day as one (preferred) up to two single doses.

Use in newborns

The daily dose in newborns is 4-7 mg/kg of body weight per day.
Due to the longer half-life, newborns are given the required daily dose in one single dose.

Use in elderly

The dose for the elderly will be adjusted accordingly.

Use in patients with kidney problems

The dose for patients with kidney problems will be adjusted accordingly.

If you are given more Genticin Injectable than you should

Overdosing is unlikely. If it does happen the doctor will treat any symptoms that follow.
Symptoms of overdose include dizziness, a feeling of spinning and hearing loss.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice:

- itching or skin rashes
- swelling of the face, lips or throat
- difficulty in breathing or wheeziness; **tell your doctor immediately.**

These may be signs of an allergic reaction.

Tell your doctor or nurse immediately if you experience:

- problems with your kidney function
- difficulty in breathing following surgery
- muscle weakness.

Other side effects include:

Uncommon: may affect up to 1 in 100 people

- feeling or being sick

- sore mouth
- increased in your liver enzymes (Aspartate/alanine aminotransferase, blood bilirubin)
- blood disorders.

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

- diarrhoea
- stomach pain
- electrolyte disturbances (changes in the levels of salts in the blood).

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

- problems with your brain
- fits, confusion, hallucinations, tiredness and depression
- acute kidney failure
- high urine levels of phosphate and amino acids (so called Fanconi-like syndrome, associated with high doses given over long time).

Not known: frequency cannot be estimated from the available data

- symptoms of increased urination, swelling in legs, ankles, breathlessness, loss of appetite, sleeping difficulty. These could be a sign of kidney failure
- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- symptoms of bruising, discolouration of skin, small red spots. These could be a sign of purpura
- problems with your ears that causes a loss of balance
- irreversible hearing loss, deafness.

Reporting of side effects

If you get any 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 directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Gentecin Injectable

Keep this medicine out of sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP:. The expiry date refers to the last day of that month.

Do not store above 25°C. Do not freeze.

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

6. Contents of the pack and other information

What Gentecin Injectable contains

- The active substance is gentamicin sulfate. Each 2 ml ampoule contains gentamicin sulfate (equivalent to 80 mg gentamicin base).
- The other ingredients are water for injection and sulfuric acid.

What Genticin Injectable looks like and contents of the pack

Genticin Injectable is a clear colourless to pale yellow solution.

It is available in 2 ml clear glass ampoules in boxes of 10 x 2 ml ampoules.

Marketing Authorisation Holder

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