

Package leaflet: Information for the patient

Genticin® 80mg/2ml Solution for Injection
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.

The name of your medicine is Genticin 80mg/2ml Solution for Injection it will be called Genticin Injection for ease here after.

What is in this leaflet

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

The name of your medicine is Genticin Injection. This medicine contains the active ingredient gentamicin which belongs to a group of medicines called antibiotics.

Genticin Injection 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 Injection

You should not be given Genticin Injection:

- if you are allergic to gentamicin or to a similar medicine containing an aminoglycoside antibiotic or any of the other ingredients of this medicine (listed in section 6)
- 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 Injection:

- if you have any problems with your kidney or liver
- if you have any problems with your 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 Gentamicin Injection
- 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
- if you are taking medicines that may adversely affect the kidneys and hearing (i.e. cephaloridine and furosemide)
- as you should not take Gentamicin Injection for more than 7 days unless you have a severe and complicated infection.

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

Talk to your doctor or pharmacist if you experience severe diarrhoea.

Monitoring tests

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 your treatment to prevent damage to your ears. Your doctor may also monitor your hearing, your balance and to assess how your kidneys and liver are working. Monitoring should occur before, after and during treatment with Gentamicin Injection. This monitoring applies to all patients, inclusive of adults, elderly, children and adolescents. (This also includes patients with kidney and/or liver disease and overweight patients).

The dose of Gentamicin Injection that you will be given by the doctor or nurse will depend strictly on how well your kidneys are functioning.

Other medicines and Gentamicin Injection

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 (particularly cephalexin), vancomycin or other aminoglycoside antibiotics (if taken with Gentamicin, this may adversely affect the kidneys and your hearing)
- ciclosporin (used to stop the body rejecting bone marrow or organ transplants)
- cisplatin and fludarabine (chemotherapy drugs)
- amphotericin (used to treat fungal infections)
- furosemide and piretanide (used as diuretics to treat heart problems) may increase the ear toxicity of gentamicin
- muscle relaxants
- medicines used to treat myasthenia gravis such as neostigmine and pyridostigmine
- indomethacin (an anti-inflammatory)
- bisphosphonates (used to treat osteoporosis)
- oral anticoagulants (used to thin the blood)
- botulinum toxin (Botox) (used in cosmetic procedures or to reduce sweating)
- any medicines that can potentially cause kidney or hearing problems
- methoxyflurane (an anaesthetic gas), the Anaesthetist should know if you are receiving gentamicin before performing anaesthesia using methoxyflurane (type of gas that should be avoided to avoid kidney damage).

If you are undergoing an operation, tell your anaesthetist if you have received or are receiving any other aminoglycoside-type antibiotics such as this medicine, before anaesthesia is administered. This will help your anaesthetist to choose the correct treatment for you.

- you will be monitored very carefully if you receive gentamicin before, during or after treatment with other medicinal products that may have possibly damaging effects on the ear nerve and kidneys.

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 being given this medicine.

Pregnancy

Gentacin Injection is not recommended for use in pregnancy unless considered appropriate by your doctor.

Breast-feeding

Breast-feeding is not recommended whilst using Gentacin Injection if you are suffering from kidney problems.

Gentamicin is released into the breast milk. Diarrhoea and fungal infection of the mouth may occur in the breast-fed infant whilst the mother is being treated with this antibiotic. It is advised that breast-feeding is stopped and an alternative feeding program (i.e. formula bottle fed) is given to your child during treatment with this antibiotic. Your baby may develop an allergic reaction if it is continued to be breast-fed whilst mother is receiving Gentacin Injection.

Driving and using machines

Caution is advised when driving and using machines in view of the possible undesired effects such as dizziness and vertigo.

3. How you will be given Gentacin Injection

The medicine will be given to you by a doctor or nurse as an injection into the muscle (i/m) or vein (i/v), it can also be given as a drip (infusion). Your doctor will work out the dose which is suitable for you.

Your blood levels of the gentamicin will be carefully monitored by the doctor or nurse examining blood samples taken at the end of a dosage interval and immediately after the end of the infusion, mainly in order to control your kidney function. Your dose will carefully be adjusted in order to avoid kidney damage.

Your treatment with gentamicin will not last longer than 7 days unless you have a severe and complicated infection.

The recommended dose in children, adolescents and adults with normal kidney function is 3-6 mg/kg of body weight per day as 1 (preferred) up to 2 single doses. In life-threatening infections, the frequency of dosage or total dosage may need to be increased by your doctor.

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 patients with kidney problems

Caution must be taken regarding dosage. Your doctor or nurse will calculate the amount of medicine you should receive.

Patients receiving kidney dialysis

Caution must be taken regarding dosage. Your doctor or nurse will calculate the amount of medicine you should receive.

Use in patients with liver problems

Caution must be taken regarding dosage. Your doctor or nurse will calculate the amount of medicine you should receive.

Use in elderly patients

The dose for the elderly will be adjusted accordingly.

Use in overweight patients

The dosage of medicine will be adjusted to compensate for the body weight.

If you are given more Gentamicin injection than you should

At first treatment will be stopped, there is no specific antidote. Overdosing is likely. 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, pharmacist or nurse.

4. Possible side effects

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

Under certain conditions, gentamicin shows toxic effects on the ear nerve and kidneys. Kidney damage is commonly observed in patients treated with gentamicin and will usually resolve after withdrawal of the drug. In most cases, kidney toxicity is associated with an excessively high dosage or long lasting treatment, already existing kidney abnormalities or is associated with other substances also having a toxic effect on kidneys. Additional risk factors for kidney toxicity are advanced age, low blood pressure, decreased blood volume or shock or existing liver disease. Risk factors for toxic effects on the ear nerve are existing liver or hearing impairment, bacteria in the blood and fever.

Tell your doctor immediately if you notice:

- An itchy, lumpy rash (hives) or nettle rash (urticaria)
- Swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing or wheeziness
- Fainting, dizziness, feeling lightheaded (low blood pressure).

These may be signs of an allergic reaction (including serious allergic reactions such as anaphylaxis).

Tell your doctor or nurse immediately if you experience:

- 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.
- difficulty in breathing or wheeziness after surgery, this may be due to the medicine affecting your breathing
- Severe allergic reaction of the skin and mucous membranes accompanied by blistering and reddening of the skin which might in very severe cases affect inner organs and might be life threatening (Stevens-Johnson syndrome, toxic epidermal necrosis)

Common (may affect up to 1 in 10 people):

- kidney function impairment (usually resolving after stop of treatment)
- problems with your kidney function

Uncommon (may affect up to 1 in 100 people):

- blood disorders such pancytopenia (low levels of white and red blood cell)

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

- being sick (vomiting), Feeling sick (nausea)
- sore mouth

- increased saliva
- muscle pain (myalgia)
- stomach pain
- electrolyte disturbances (changes in the levels of salts such as magnesium, calcium and potassium in the blood)
- problem with your liver
- changes in liver function (indicated by change in your liver enzymes)
- loss of appetite, weight loss.
- blood urea nitrogen increased (reversible)
- disturbances in the peripheral nerves causing tingling or prickling, “pins-and-needles” sensation; often occurs in the arms, hands, legs or feet.
- drug fever

Very Rare (may affect up to 1 in 10,000 people):

- problems with your brain (brain disease)
- convulsions
- blockage of nerve and muscle function
- dizziness
- infection with other gentamicin-resistant germs
- pseudomembranous colitis (inflammation of the intestines due to antibiotics, also known as antibiotic associated diarrhoea characterised by diarrhoea with or without blood, abdominal pain and fever).
- abnormally low counts of different blood cell types, increased count of eosinophils (a certain group of white blood cells). Leukopenia, granulocytopenia, neutropenia (low white blood cell counts), thrombocytopenia (reduction in platelet count), reticulocytopenia (abnormal decrease of reticulocytes in the body, which are immature red blood cells.)
- anaemia (reduction in red blood cells which can make the skin pale and cause weakness or breathlessness).
- fits, confusion, hallucinations, tiredness and depression
- high blood pressure
- low blood pressure
- problems with your vision
- pain at the site where injection is given
- muscle tremor (causing difficulty in standing)
- hair loss
- headache
- acute kidney failure

- high urine levels of phosphate and amino acids (so called Fanconi-like syndrome, associated with high doses given over long time).
- low level of phosphate in the blood

Not known (frequency cannot be estimated from the available data):

- symptoms of bruising, discolouration of skin, small red spots. These could be a sign of purpura
- rash
- pruritus
- irreversible hearing loss, deafness.

Reporting of side effects

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

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Genticin Injection

Keep this medicine out of the sight and reach of children.

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

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

For single use only. Discard any portion of the contents remaining after use.

Do not use this medicine if you notice that the solution is no longer colourless to pale yellow or contains visible particulates.

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 Genticin Injection contains

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

What Genticin Injection looks like and the content of the pack

Genticin Injection is a clear colourless to pale yellow solution.
It is available in 2ml clear glass ampoules in boxes of 10 x 2ml ampoules.

Marketing Authorisation Holder

Amdipharm UK Limited
Capital House
85 King William Street
London EC4N 7BL. UK

Manufacturer

Farmar S.A.
Agiou Dimitriou 63,
Alimos Attiki,
17456
Greece

This leaflet was last revised in March 2024.

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