

Package leaflet: Information for the user

GENTAMICIN 10MG/ML SOLUTION FOR INJECTION OR INFUSION
and
GENTAMICIN 40MG/ML SOLUTION FOR INJECTION OR INFUSION

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor or pharmacist
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What gentamicin is and what it is used for

The name of this medicine is Gentamicin 10mg/ml Solution for Injection or Infusion and Gentamicin 40mg/ml Solution for Injection or Infusion (called "gentamicin" in this leaflet).

It contains a medicine called gentamicin sulfate. This belongs to a group of antibiotics called aminoglycosides.

Gentamicin is used to treat infections caused by bacteria. This includes infections in:

- Your urinary tract (including your kidneys or bladder)
- Your chest (including your lungs)
- Your abdomen (including your gut)
- Your brain and spinal cord
- Your blood – this is sometimes called 'bacteraemia' or 'septicaemia'
- Newborn babies.

2. What you need to know before you take gentamicin

Do not take Gentamicin if:

- You are allergic (hypersensitive) to gentamicin, any other antibiotics or to any of the other ingredients of this medicine (see section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat and tongue
- You have myasthenia gravis. This is a disease that causes muscle weakness.

Do not use this medicine if any of the above applies to you. If you are not sure, talk to your doctor or nurse before using gentamicin.

Warning and precautions

Talk to your doctor or pharmacist before taking Gentamicin if:

- You are pregnant, think you may be pregnant or are planning to have a baby
- You are breast-feeding or are planning to breast-feed
- You have any muscle weakness problems
- You are extremely overweight (obese)
- You have kidney problems
- You have cystic fibrosis
- You are elderly (over 65 years of age) or the patient is less than 1 year old
- You know (or think) you have a mitochondrial disease (mutations in the parts of your cells which help make energy). Certain mitochondrial diseases may increase your risk of hearing loss with this product
- 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
- You experience severe diarrhoea
- You develop severe skin reactions such as Stevens-Johnson Syndrome (SJS) or toxic epidermal necrolysis (TEN) as described in section 4 "Possible side effects". If you have symptoms of a severe skin reaction, contact your doctor or nurse immediately.

Your doctor will need to monitor you before, during and shortly after your treatment. Your doctor may check your hearing, balance, how your kidneys are working and the amount of gentamicin in your blood.

This is to prevent damage to your ears and/or kidneys and is particularly important if you have kidney problems, are obese, suffer from cystic

fibrosis or are over 65 years of age, or the patient is less than 1 year old.

If you are not sure if any of the above applies to you, talk to your doctor or nurse before using gentamicin.

Other medicines and Gentamicin

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because gentamicin can affect the way some other medicines work. Also, some medicines can affect the way gentamicin works.

In particular tell your doctor if you are taking any of the following:

- Medicines used to thin the blood such as warfarin
- Water tablets or injections (diuretics) such as furosemide or etacrynic acid
- Amphotericin B - used to treat fungal infections
- Cephalosporin antibiotics such as cephaloridine – used to treat bacterial infections
- Ciclosporin - used in organ transplants or for severe skin problems
- Neostigmine or pyridostigmine – used to treat Myasthenia Gravis
- Muscle relaxants - sometimes used during operations which need an anaesthetic
- Indometacin - used to treat pain or swelling
- Bisphosphonates - used to treat osteoporosis
- Cisplatin (used to treat some cancers)
- Botulinum toxin – used to lower the activity of overactive muscles. This is also sometimes used in cosmetic procedures (botox).

These medicines may increase the chances of getting certain side effects. If you are unsure about any of the above, consult your doctor or nurse.

Pregnancy and breast-feeding

Gentamicin is not recommended during pregnancy or breast-feeding.

Ask your doctor or nurse for advice before having this medicine if:

- You are pregnant, think you may be pregnant or are planning to have a baby
- You are breast-feeding or are planning to breast-feed.

Gentamicin 10mg/ml contains sodium metabisulfite, which may rarely cause severe allergic reactions and difficulty in breathing. This medicine contains 0,78mg of sodium per ampoule (less than 23mg per ampoule), i.e. it is essentially sodium free.

3. How to take Gentamicin

Gentamicin is always given to you by a doctor or nurse. This is because it needs to be given as an injection.

Using this medicine

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, in particular diseases of the kidney.

Tests

Blood samples will be taken by your doctor or nurse to check the dose is right for you. You should not receive Gentamicin if these blood tests cannot be performed. You may also need tests to check your hearing and balance.

Elderly or obese people, newborns, people with impaired kidney function and those with cystic fibrosis should be particularly closely monitored when using this medicine.

How much Gentamicin is given

Adults

- The usual daily dose in adults is 3-5mg for each kg of body weight
- This is given either as one single dose (preferred) or split into two or three daily doses
- This dose may be increased or decreased by your doctor depending on your illness and the results of your blood tests
- If you have kidney problems your doctor may give you a lower dose or may prolong the interval between doses.

The following information is intended for medical or healthcare professionals only:

Monitoring

To avoid adverse events, continuous monitoring (before, during and after treatment) of renal function (serum creatinin, creatinin clearance), control of function of vestibule and cochlea as well as hepatic and laboratory parameters is recommended.

In order to reduce the risk of nephrotoxicity and ototoxicity, the following instructions should be considered:

- Regular assessment of auditory, vestibular and renal function is particularly necessary in patients with additional risk factors. Impaired hepatic function or auditory function, bacteraemia and fever have been reported to increase the risk of ototoxicity. Volume depletion or hypotension and liver disease have been reported as additional risk factors for nephrotoxicity.

- Monitoring of renal function before, during and after treatment.
- Dosage strictly according to creatinine clearance (or serum creatinine concentration). In patients with impaired renal function, the dosage must be adjusted according to renal performance (see section 4.2).
- In patients with impaired renal function additionally receiving gentamicin locally (inhalation, intratracheal, instillation), the amount of gentamicin absorbed after local administration must also be taken into account for dose adjustment of systemic treatment.
- Monitoring of serum gentamicin concentrations during therapy in order to avoid that peak levels exceed 10 µg/ml (toxic threshold for the cochleo-vestibular system) with conventional multiple daily dosing or trough levels exceed 2 µg/ml (see section 4.2) when administering gentamicin twice daily and 1mg/l for a once daily dosing.

Use in children and adolescents

Children (aged 1 year and above)

- The usual daily dose is 3-6mg for each kg of body weight
- This is given either as one single dose (preferred) or split into two separate doses.

Babies (aged 4 weeks to 1 year)

- The usual daily dose is 4.5 to 7.5mg for each kg of body weight
- This is given either as one single dose (preferred) or split into two separate doses.

Premature babies or new born babies (up to 4 weeks):

- The usual daily dose is 4 to 7mg for each kg of body weight
- This is given in one single dose.

If you use more gentamicin than prescribed

It is most unlikely that you will be given too much medicine by the doctor or nurse.

Your doctor or nurse will be checking your progress and checking the medicine that you are given. Ask if you are not sure why you are getting a dose of medicine.

If you miss a dose of gentamicin

Your doctor or nurse have 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 nurse or doctor.

If you stop taking gentamicin

It is important that the course of treatment your doctor has prescribed is finished.

You may start to feel better but it is important to continue your treatment until the doctor advises. If you stop, your infection may get worse again.

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 of the following serious side effects- you may need urgent medical treatment:

Not known (frequency cannot be estimated from available data)

- Allergic reactions (including serious allergic reactions such as anaphylaxis), which may include:
- 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
 - Fainting, dizziness, feeling lightheaded (low blood pressure).

Severe allergic reaction of the skin and mucous membranes accompanied by blistering, peeling, bleeding and reddening of any part of the skin (including the lips, eyes, mouth, nose, genitals, hands or feet) with or without a rash. You may also have flu-like symptoms such as fever, chills or aching muscles. In very severe cases this might affect inner organs and might be life-threatening (Stevens-Johnson syndrome, toxic epidermal necrolysis).

Tell your doctor or nurse as soon as possible if any of the following side effects happen:

Very rare side effects (may affect less than 1 in 10,000 people)

- Acute kidney failure, which may cause you to pass less urine than is normal for you, fluid retention, breathlessness or fatigue/tiredness.

Not known (frequency cannot be estimated from available data)

- Temporary or irreversible hearing loss or deafness
- Unusual difficulty in moving which has not happened before
- Numbness, weakness and pain in the arms and legs (peripheral neuropathy)
- Blood in the urine
- Diarrhoea, with or without blood and/or stomach cramps
- Infection with other gentamicin-resistant germs.

Tell your doctor or nurse if any of the following side effects gets serious or last longer than a few days. Also tell them if you notice any side effects not listed in this leaflet

Very common side effects (may affect more than 1 in 10 people)

- Feeling sick (vomiting).

Not known (frequency cannot be estimated from available data)

- Feeling sick (nausea)
- Mouth ulcers
- Rash, itching or a purplish or reddish-brown skin colouring
- Depression
- Seeing or hearing things that are not real (hallucinations)
- Feeling confused, tired or weak
- Fits.

Other possible side effects:

Very rare side effects (may affect less than 1 in 10,000 people)

- High levels of phosphate and amino acids (so-called Fanconi-like syndrome, associated with high doses given over a long time)

Not known (frequency cannot be estimated from available data)

- Changes in the number of blood cells (including anaemia) – shown up in the results of blood tests
- Changes in the amount of liver enzymes – shown up in the results of blood tests
- A decrease in the level of magnesium in the blood, associated with prolonged therapy.

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 at: 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 Gentamicin solution for injection or infusion

- This medicine will be kept by your doctor or nurse in a safe place out of the sight and reach of children
- Do not use this medicine after the expiry date which is stated on the carton and on the ampoule after "Exp.". The expiry date refers to the last day of that month. If you are not sure when this is, check with your doctor or nurse
- Do not store this medicine above 25°C. Do not keep this medicine in a fridge or freezer. You will not be asked to store your medicine. It will be brought to you ready to be given straight away
- Do not throw away any medicines via household waste. These measures will help protect the environment.

6. Contents of the pack and other information

What gentamicin solution for injection or infusion contains

- The active substance is gentamicin as gentamicin sulfate
- The other ingredients are sulfuric acid or sodium hydroxide (for pH adjustment), sodium metabisulfite (E223) and water for injections.

Each 2ml ampoule of Gentamicin 10mg/ml Solution for Injection or Infusion contains the equivalent of 20mg of gentamicin.

Each 2ml ampoule of Gentamicin 40mg/ml Solution for Injection or Infusion contains the equivalent of 80mg of gentamicin.

What gentamicin solution for injection or infusion looks like and content of the pack

The medicine is a clear, colourless solution for injection or infusion in 2ml ampoules.

Gentamicin 10mg/ml is available in packs containing 5 ampoules.

Gentamicin 40mg/ml is available in packs containing 5 or 10 ampoules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:
0800 198 5000 (UK only)

Please be ready to give the following information:

Product name	Reference Number
Gentamicin 10mg/ml Solution for Injection or Infusion	PL 29831/0659
Gentamicin 40mg/ml Solution for Injection or Infusion	PL 29831/0660

This is a service provided by the Royal National Institute of Blind People.

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- In patients with pre-existing inner ear damage (hearing impairment or balance function impairment), or where treatment is long-term, additional monitoring of the balance function and hearing is required.
- Prolonged treatment should be avoided. If possible, the duration of therapy should be limited to 7 – 10 days (see section 4.2).
- Avoid therapy with aminoglycosides immediately subsequent to previous aminoglycoside treatment; if possible, there should be an interval of 7 – 14 days between treatments.
- If possible, avoid concurrent administration of other potentially ototoxic and nephrotoxic substances. If this is unavoidable, particular careful monitoring of renal function is indicated (see section 4.5).
- Ensure adequate hydration and urine production.

Instructions for administration and dilution

After first opening: from the microbiological point of view, the product should be used immediately.

Gentamycin can be diluted with 0.9% sodium chloride or 5% glucose solution. After dilution gentamicin is stable for 24 h at 25°C.

Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C.

From a microbiological point of view, unless the method of opening/dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

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