Gentamicin 10mg/ml & 40mg/ml Solution for Injection or Infusion

1. WHAT GENTAMICIN IS AND WHAT IT IS USED FOR

Gentamicin is a medicine called gentamicin sulfate. This belongs to a group of antibiotics called aminoglycosides.

Gentamicin is used to treat infections caused by bacteria in adults and children (including newborns). This includes infections in:

- Your urinary tract (including your kidneys or bladder)
- Your chest (including your lung)
- Your blood is this sometimes called ‘bacteremia’
- Other serious infections

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE GENTAMICIN

Do not take Gentamicin if:

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

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking gentamicin.

3. HOW TO TAKE GENTAMICIN

The recommended dose is stated below and apply to both of the medicines shown at the heading of this leaflet.

- Always take this medicine exactly as your doctor or pharmacist has told you. The recommended dose is stated below and apply to both of the medicines shown at the heading of this leaflet.

4. POSSIBLE SIDE EFFECTS

Medicines and that may determine additional toxicity to kidneys and ear damage:

- Water balance or injections (diuretics): such as furosemide or etacrinic acid
- Ampicillin (used to treat bacterial infections)
- Cephalosporins such as cephradine or other antibiotics
- Clindamycin (used in organ transplants or for severe skin problems)
- Ciprofloxin (used to treat some cancers)
- Neostigmine or pyridostigmine (used to treat Myasthenia Gravis): these may cause the effect of gentamicin
- Muscle relaxants and ether - sometimes used during operations
- Neostigmine or pyridostigmine (used to treat Myasthenia Gravis): these may cause the effect of gentamicin
- Neostigmine or pyridostigmine (used to treat Myasthenia Gravis): these may cause the effect of gentamicin
- Other aminoglycosides

5. HOW TO STORE GENTAMICIN

Gentamicin is always given to you by a doctor or nurse. It is usually given into a vein, it can either be given as an injection or dissolved with e.g. saline or 5% glucose in water and given as a slow injection via a drip (infusion).

Driving and using machines

Gentamicin can enhance its effects on nerve and muscle function

- You are breast-feeding or planning to breast-feed.
- You have kidney problems, are over 65 years of age
- You experience severe diarrhoea.
- You are allergic to any of the ingredients of this medicine (listed in section 6).
- You have pre-existing cancer.
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- You have pre-existing cancer.

If you are not sure of any of the above applies to you, talk to your doctor or pharmacist before taking gentamicin.

Children

Gentamicin is only given to children by a doctor or nurse. If it is given to a vein, it can either be given as an injection or dissolved with e.g. saline or 5% glucose in water and given as a slow injection via a drip (infusion).

Your doctor will decide how much to give, depending on your weight. The correct dose also depends on the type of infection and any other illness you may have.

Blood samples will be taken by your doctor or nurse to check the dose amount you need. Always talk to your doctor exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is stated below and apply to both of the medicines shown at the heading of this leaflet.

Adults

- The usual daily dose in adults is 1-5mg for each kg of body weight.
- This is split into doses given every 6-8 hours.
- The dose may be increased or decreased by your doctor depending on your illness.

6. CONTENTS OF THE PACK AND OTHER INFORMATIONS

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Changes in detail:

- Regulatory text amends
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4. POSSIBLE SIDE EFFECTS

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

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

- It becomes difficult keeping your balance, you feel dizzy or your hearing becomes poor. This may happen in gentamicin can sometimes damage the ear. This is more likely to happen if your kidney does not work very well.
- You notice anything unusual when you pass water, such as any signs of blood in your water (urine) or you find you are passing less water than is normal for you.
- You may have pain in your kidneys.
- You may have unusual difficulty in swallowing which has not happened before, feel weak or unusually tired or have any breathing difficulties that have not happened before.
- You may have a severe headache or muscle problems.

- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having an allergic reaction to gentamicin.

- If you notice any of the above, talk to your doctor or nurse as soon as possible.

Other possible side effects of gentamicin are:

- Discomfort (pain) in (100 people): abnormal blood composition
- Nausea (may affect up to 1 in 100 people): low blood levels of potassium, calcium and magnesium, loss of appetite, weight loss, damage of peripheral nerves, impairment of hearing, vomiting, sickness, increased salivation, inflammation in the mouth, increased levels of liver enzymes and blood platelets, muscle pain, increased levels of blood sebum, increased body temperature
- Any other (may affect up to 1 in 10,000 people): infection with other, gentamicin-resistant germs, drug fever, confusion, hallucinations, nerve damage, impaired balance, headache, impairment of vision, ear pain, decreased blood pressure, increased blood pressure, hair loss, pain at injection site, acute kidney failure, high levels of phosphate and amino acids (so-called Fanconi syndrome, associated with high doses over a longer period), severe allergic reaction of the skin and muscles membranes accompanied by blistering and reddening of the skin (Stevens-Johnson syndrome), which might in very severe cases affect inner organs and might be life threatening (Stevens-Johnson syndrome, toxic epithelial necrosis).
- Not known (frequency cannot be estimated from the available data): Incurable hearing loss, deafness.

4.2. 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 national reporting systems below.

4.3. Reporting of side effects

- If you forget to take gentamicin

Your doctor or nurse will give you a dose that is right for you. You may have missed a dose then talk to your nurse or doctor.

4.4. 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 it until the treatment is over and the doctor advises otherwise. If you stop, your infection may get worse again.

5. HOW TO STORE GENTAMICIN

The product is a clear, colourless solution for injection or infusion in a glass ampoule.

- The other ingredients are sulfuric acid or sodium hydroxide (for pH adjustment), sodium metabisulfite (E223) and water for injections.

- The active substance is gentamicin as gentamicin sulfate.

- Each 2 ml ampoule contains the equivalent of 80mg of gentamicin.

- Each 2 ml ampoule contains the equivalent of 20mg of gentamicin.

- Each 2 ml ampoule contains the equivalent of 10mg of gentamicin.

- The other ingredients are sulfuric acid or sodium hydroxide (for pH adjustment), sodium metabisulfite (E223) and water for injections.

- The active substance is gentamicin as gentamicin sulfate.

- Gentamicin can be diluted with 0.9% sodium chloride or 5% glucose solution.

- Gentamicin is not given by an injection into the eye.

- Gentamicin is not given by an injection into the skin.

- Gentamicin is not given by an injection into the mouth.