Contents of the pack and other information
• Newborn babies.

How to store gentamicin solution for injection or infusion
1. Keep this leaflet. You may need to read it again.
2. If you are not sure if any of the above applies to you, talk to your doctor or nurse before using gentamicin.

What is gentamicin and what is it 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.

How to take gentamicin

3. How to take gentamicin

Dose and method of administration

- Regular assessment of auditory, vestibular and renal function is particularly necessary in patients additionally receiving gentamicin locally (inhalation, intratracheal, instillation), the administration must also be taken into account for dose adjustment of systemic treatment.
- Monitoring of auditory function or auditory function, bacteraemia and septicaemia.
- Severely impaired kidney function and those with cystic fibrosis (mutations in the parts of your cells which help make energy). Certain mitochondrial disease may increase your risk of hearing loss with this product.
- Experience severe diarrhoea.
- Develop severe skin reactions such as Steven-Johnson Syndrome (SJS) or toxic epidermal necrolysis (TEN) (described in section 4 “Possible side effects”). If you have symptoms of a severe skin reaction, contact your doctor or nurse immediately.
- This dose may be increased or decreased by your doctor depending on your illness and the results of tests.
- Give you a lower dose or may prolong the interval between doses.
- Split into two separate doses.
- 2. 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 allergic reaction include: a rash, swelling, 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.

Ask your doctor or pharmacist for advice before having any vaccines.

• You are pregnant, you may be pregnant or are planning to have a baby.
• You are elderly (over 65 years of age) or the kidneys are working and the amount of gentamicin in your body is the same as your age.
• You have kidney problems.
• Medicines used to thin the blood such as warfarin — anticoagulants.
• Cephalosporin antibiotics such as cephaloridine — any cephalosporin antibiotics (e.g. cefotaxime, cefuroxime).
• Water tablets or injections (diuretics) such as furosemide or etacrynic acid.
• Ciclosporin - used in organ transplants or for transplant rejection.
• Indometacin - used to treat pain or swelling.
• Neostigmine or pyridostigmine - used to treat overactive muscles. This is also sometimes used in cosmetic procedures (botox).
• You are breast-feeding or are planning to breast-feed.

Gentamicin 10 mg/ml contains sodium metabolites, which may rarely cause severe allergic reactions including anaphylaxis in patients with a history of allergy to these substances.
This medicine contains 0.78 mg of sodium per ampoule, i.e. 0.23 mg per ampoule. It is essentially sodium free.

Gentamicin is not recommended during pregnancy.

Ask your doctor or nurse for advice before having any vaccines.

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

Gentamicin 10 mg/ml Solution for Injection or Infusion contains 0.78 mg of sodium per ml, i.e. it is essentially sodium free.

Using this medicine

coughing, difficulty in breathing, wheezing, severe skin problems

Your doctor will decide how much you give, depending on the type of infection and any other illness you may have, in particular diseases of the kidneys.

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 show that the creatinine clearance of your kidneys is too low.

You may also need tests to check your hearing and balance.

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

• You are elderly or obese people, newborns, people with impaired kidney function and those with cystic fibrosis (mutations in the parts of your cells which help make energy). Certain mitochondrial diseases may increase your risk of hearing loss with this product.

Children (aged 1 year and above)

• This is given either as one single dose (preferred) or split into two or three daily doses.

The usual daily dose in adults is 1-3 mg/kg for each dose, depending on the type of infection and any other illness you may have, in particular diseases of the kidneys.

Gentamicin is not recommended in pregnancy.

Using this medicine

• You have myasthenia gravis.

• 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.

• 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.

• Use in children and adolescents

• You have known 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.

• You experience severe diarrhoea.

• You develop severe skin reactions such as Steven-Johnson Syndrome (SJS) or toxic epidermal necrolysis (TEN) (described in section 4 “Possible side effects”). If you have symptoms of a severe skin reaction, contact your doctor or nurse immediately.

• This dose may be increased or decreased by your doctor depending on your illness and the results of your blood tests.

• You have kidney problems your doctor may give you a lower dose or may prolong the interval between doses.

The usual daily dose in adults is 1-3 mg/kg for each dose, depending on the type of infection and any other illness you may have, in particular diseases of the kidneys.

Gentamicin 10 mg/ml Solution for Injection or Infusion contains 0.78 mg of sodium per ml, i.e. it is essentially sodium free.

Gentamicin is not recommended during pregnancy.

Using this medicine

• You should not receive Gentamicin if these blood tests show that the creatinine clearance of your kidneys is too low.

You may also need tests to check your hearing and balance.

• You are elderly or obese people, newborns, people with impaired kidney function and those with cystic fibrosis (mutations in the parts of your cells which help make energy). Certain mitochondrial diseases may increase your risk of hearing loss with this product.

Children (aged 1 year and above)

• The usual daily dose is 3-5 mg/kg for each kg of body weight.

• This is given either as one single dose (preferred) or split into two separate doses.

The usual daily dose in adults is 1-3 mg/kg for each kg of body weight.

• This is given either as one single dose (preferred) or split into two separate doses.

— Monitoring of renal function before, during and after treatment.
— Dosage according to creatinine clearance (or serum creatine concentration). In patients with impaired renal function, the dosage must be adapted (see section 4.2).
— In—patients with impaired renal function additionally receiving gentamicin locally (e.g. by instillation), the amount of gentamicin absorbed after local administration may also be taken into account for dose adjustment of systemic treatment.
— Monitoring of auditory function or auditory function, bacteraemia and septicaemia.
— Severely impaired kidney function and those with cystic fibrosis (mutations in the parts of your cells which help make energy). Certain mitochondrial diseases may increase your risk of hearing loss with this product.

• 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.

• Use in children and adolescents

• The usual daily dose is 3-5 mg/kg for each kg of body weight.

• This is given either as one single dose (preferred) or split into two separate doses.

The usual daily dose in adults is 1-3 mg/kg for each kg of body weight.

• This is given either as one single dose (preferred) or split into two separate doses.

— Monitoring of renal function before, during and after treatment.
— Dosage according to creatinine clearance (or serum creatine concentration). In patients with impaired renal function, the dosage must be adapted (see section 4.2).
Premature babies or new born babies (up to 4 weeks):

Your doctor or nurse will be checking your progress and checking the medicine that you are using. It is very unlikely that you will not be given too much medicine by the doctor or nurse. If you use more gentamicin than prescribed you will not be given the medicine as it has been prescribed. If you think that you have missed a dose then talk to your doctor or nurse.

If you miss a dose of gentamicin

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.

If you use more gentamicin than prescribed

• This medicine will be kept by your doctor or nurse in a safe place out of the sight of 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.
• Not to be stored 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 including the empty pack.

5. How to store Gentamicin solution for injection or infusion contains:

• The active substance is gentamicin as gentamicin sulphate
• Other ingredients are sulphuric acid or sodium hydroxide (for pH adjustment), sodium metabolite/hydrate and water for injections.

2 ml ampoules of Gentamicin 10mg Solution for Injection contains the equivalent of 20mg of gentamicin.

Two ml ampoules of Gentamicin 40mg Solution for Injection contains the equivalent of 80mg of gentamicin.

What gentamicin solution for injection or infusion contains:

• 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.

Other forms:

Not to be mixed with other substances.

Not to be added to any other medicines.

Not to be used with dialysis.

Not to be used in any extractor system.

Not to be used in any reverse osmosis system.

Not to be used in any oxygen therapy systems.

Not to be used in any pre dialysis system.

Not to be used in any post dialysis system.

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