PATIENT INFORMATION LEAFLET
GENTAMICIN PAEDIATRIC 20MG/2ML SOLUTION FOR INJECTION

Read all of this leaflet carefully before you start taking this medicine.
• 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
• If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
• Your doctor may have given you this medicine before from another company. It may have looked slightly different. However, either brand will have the same effect.

In this leaflet:
1. What gentamicin is and what it is used for
2. Before you have gentamicin
3. How to have gentamicin
4. Possible side effects
5. How to store gentamicin
6. Further information

1. What gentamicin is and what it is used for

The name of this medicine is Gentamicin Paediatric 20mg/2ml Solution for Injection (called gentamicin in this leaflet). It contains a medicine called gentamicin sulphate. 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 blood – this is sometimes called ‘bacteraemia’ or ‘septicaemia’
• Newborn babies

2. Before you have gentamicin

Do not have this medicine 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 (see Section 6: Further Information).
  Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat and tongue.
Do not have this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before having gentamicin.

Take special care with gentamicin and check with your doctor or pharmacist before having your medicine if:
• You are pregnant, might become pregnant, or think you may be pregnant.
• You are breast-feeding (see ‘Pregnancy and breast-feeding’ section below)
• You have any muscle weakness problems
• You are extremely overweight
• You have kidney problems, are over 65 years of age or the patient is less than 1 year old. This is because your doctor will need to keep a careful eye on you during your treatment, to prevent damage to your ears.
He may check your hearing, your balance, how your kidneys are working and the amount of gentamicin in your blood. If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before having gentamicin.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained 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
- Ciclosporin (used in organ transplants or for severe skin problems)
- Neostigmine or pyridostigmine (used to treat Myasthenia Gravis)
- Cephalosporin antibiotics such as cephaloridine
- 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.

These medicines may increase the chances of getting certain side effects (see Section 4: Possible side effects). If you are unsure about any of the above, consult your doctor.

Pregnancy and breast-feeding
Talk to your doctor before having this medicine if:
- You are pregnant, think you may be pregnant or plan to get pregnant. Gentamicin should not normally be used during pregnancy.
- You are breast-feeding or planning to breast-feed

Gentamicin contains sodium. It contains 17.30mg per vial.

3. How to have gentamicin

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

Having 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. Blood samples will be taken by your doctor or nurse to check the dose is right for you.

How much gentamicin is given

Adults
- The usual daily dose in adults is 3-5mg for each kg of body weight
- This is split into doses given every 6-8 hours
- This dose may be increased or decreased by your doctor depending on your illness
- If you have kidney problems your doctor may give you a lower dose
- Elderly people should be closely monitored when having this medicine

Children (aged 1 year and above) and adolescents
• The usual daily dose is 3-6mg for each kg of body weight
• This is given either as 1 single dose (preferred) or split into 2 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 1 single dose (preferred) or split into 2 separate doses

**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 1 single dose

**If you have more gentamicin than you should**
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**
Gentamicin will be given to you by a doctor or nurse. 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 having 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, 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. Gentamicin can sometimes damage the ear. This is more likely to happen if your kidneys do not work very well.
• If you notice anything unusual when you pass water, such as any sign of blood in your water (urine) or you find you are passing less water than is normal for you. This may mean you have kidney problems.
• If you have unusual difficulty in moving which has not happened before, feel weak or unusually tired or have any breathing difficulties that have not happened before. This may mean you have nerve 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.

**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**
• Headache
• Feeling tired
• Purplish or reddish-brown skin colouring
• Mouth ulcers
• Feeling or being sick (nausea or vomiting)
• Rash
• Bloody diarrhoea, possibly with stomach pain/cramps
• Fits or convulsions
• Feeling confused
• Depression
• Strange visions or sounds (hallucinations) and memory loss
• Numbness, weakness and pain in the arms and legs (peripheral neuropathy).

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

5. **How to store gentamicin**

• You will not be asked to store your medicine. It will be brought to you ready to be given straight away.
• Keep out of the reach and sight of children.
• Do not use this medicine after the expiry date shown on the pack.
• Do not store this medicine above 25°C. Do not keep this medicine in a fridge or freezer.
• Do not dispose of medicines, which are no longer needed, by flushing down a toilet or sink or by throwing out with your normal household rubbish. This will help protect the environment.

6. **Further information**

**What gentamicin contains**
The active substance is gentamicin sulphate, each vial contains the equivalent of 20mg of gentamicin. The other ingredients are sulphuric acid and sodium hydroxide (for pH adjustment), sodium chloride and water for injections.

**What gentamicin looks like and content of the pack**
The medicine is a clear, colourless solution for injection in 2ml vials. Gentamicin is available in packs of 5 vials.

The **Marketing Authorisation Holder is:** Zentiva, One Onslow Street, Guildford, Surrey, GU1 4YS, UK

The **Manufacturer is:** Famar Health Care Services Madrid, S.A.U, Avda. Leganes 62, Alcorcon, 28923 Madrid, Spain

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