

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

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, ask your doctor or nurse.
- 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 nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- 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.

What is in this leaflet:

1. What gentamicin is and what it is used for
2. What you need to know before you have gentamicin
3. How to have gentamicin
4. Possible side effects
5. How to store gentamicin
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 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 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 have gentamicin

Do not have gentamicin if you:

- X 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.
- X have myasthenia gravis. This is a disease that causes muscle weakness.

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before having gentamicin if you:

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

- have any muscle weakness problems.
- are extremely overweight.
- 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 monitor you before, during and shortly after 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.
- 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 are not sure if any of the above applies to you, talk to your doctor or nurse before having gentamicin.

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

Other medicines and gentamicin

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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).
- 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. If you are unsure about any of the above, consult your doctor or nurse.

Pregnancy and 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. Gentamicin should not normally be used during pregnancy.
- are breast-feeding or are planning to breast-feed.

Gentamicin contains sodium

This medicine contains 6.81 mg of sodium per 2 ml 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.

Use in children and adolescents

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 4.5-7.5mg for each kg of body weight.
- This is given either as 1 single dose (preferred) or split into 2 separate doses.

Premature or new born babies (up to 4 weeks)

- The usual daily dose is 4-7mg 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, 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 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)

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
- 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)

- 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, passing less urine than is normal for you
- Changes in the blood cells – 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
- A decrease in the number of red blood cells (anaemia)

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

Not known (frequency cannot be estimated from available data)

- Feeling sick (nausea) or being sick (vomiting)
- Diarrhoea, with or without blood and/or stomach cramps
- Inflammation of the gut (lower intestine) and mouth ulcers, associated with antibiotic use
- 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
- Infection with other gentamicin-resistant germs

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

- This medicine will be kept by your doctor or nurse in a safe place out of the sight and reach of children.
- You will not be asked to store your medicine. It will be brought to you ready to be given straight away.
- Do not store this medicine above 25°C. Do not keep this medicine in a fridge or freezer.
- Do not have this medicine after the expiry date. This is stated in month and year on the carton and on the label 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 throw away any medicines via wastewater. 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 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 contents of the pack

The medicine is a clear, colourless solution for injection in 2ml vials. Gentamicin is available in packs of 5 vials.

Marketing Authorisation Holder and Manufacturer**The Marketing Authorisation Holder is:**

Zentiva Pharma UK Limited, 12 New Fetter Lane, London, EC4A 1JP, United Kingdom

The Manufacturer is:

Famar Health Care Services Madrid, S.A.U, Avda. Leganes 62, Alcorcon, 28923 Madrid, Spain

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