

PACKAGE LEAFLET: INFORMATION FOR THE USER

GENTAMICIN INTRATHECAL 5MG/ML 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 of the 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 Intrathecal 5mg/ml 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:

- brain - including meningitis
- spinal cord

2. What you need to know before you have gentamicin

Do not have gentamicin if you:

- are allergic (hypersensitive) to gentamicin sulphate, 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.
- have myasthenia gravis or a related condition. 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 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 (obese).
- have kidney problems.
- have cystic fibrosis.
- are elderly (over 65 years of age) or the patient is less than 1 year old.
- 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, pharmacist or nurse before you take or are given 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.

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 having gentamicin.

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

Other medicines and gentamicin

Please tell your doctor or nurse 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 are planning to have a baby. Gentamicin should not normally be used during pregnancy.
- breast-feeding or planning to breast-feed.

Important information about the ingredients of Gentamicin

This medicine contains less than 1 mmol sodium (23 mg) per 1 ml ampoule, that is to say essentially 'sodium-free'.

3. How to have gentamicin

Gentamicin is always given to you by a doctor or nurse. This is because it is 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, 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 having this medicine.

How much gentamicin is given Adults and children

- The usual starting dose is 1mg a day given into the brain or spine (intraventrically or intrathecally).

- This dose may be increased or decreased by your doctor depending on your illness
- A separate injection into a muscle is given every 8 hours. This dose will be decided by your doctor depending on your bodyweight.

If you have 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

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, 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

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)

- Being sick (vomiting)

Not known (frequency cannot be estimated from available data)

- Feeling sick (nausea)
- 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

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 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.
- Store below 25°C, do not refrigerate or freeze.
- 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 ampoule contains the equivalent of 5mg of gentamicin. The other ingredients are sodium chloride and water for injections.

What gentamicin looks like and content of the pack

Gentamicin is available in packs of 5 ampoules.

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, Alcoron 28923, Madrid, Spain

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