

Gentamicine 80mg/2ml Solution for Injection

Gentamicin

What Gentamicin is and what it is used for

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

What you need to know before you have Gentamicin

Do not have Gentamicin if: You are allergic (hypersensitive) to gentamicin. Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat and tongue.

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

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. You are breast-feeding or are planning to breast-feed. You have any muscle weakness problems. You experience severe diarrhoea. You develop severe skin reactions such as Stevens-Johnson Syndrome (SJS) or toxic epidermal necrolysis (TEN) as described in section 4 "Possible side effects". If you have symptoms of a severe skin reaction, contact your doctor or nurse immediately.

- You 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.
- You are extremely overweight (obese).
- You have kidney problems.
- You have cystic fibrosis.
- You are elderly (over 65 years of age) or the patient is less than 1 year old.

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 Cidomycin.

Other medicines and Gentamicin

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines you buy 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 – used to treat bacterial infections. 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

Gentamicin is not recommended during pregnancy or 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. You are breast-feeding or are planning to breast-feed.

How to have Cidomycin

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, 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:** The usual daily dose in adults is 3-5mg for each kg of body weight.

- This is given either as one single dose (preferred) or split into two or three daily doses.
- This dose may be increased or decreased by your doctor depending on your illness and the results of your blood tests.
- If you have kidney problems your doctor may give you a lower dose or may prolong the interval between doses.

Use in children and adolescents: Children (aged 1 year and above)

- The usual daily dose is 3-6mg for each kg of body weight.
- This is given either as one single dose (preferred) or split into two 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 one single dose (preferred) or split into two separate doses.

Premature babies 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 one single dose.

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 Gentamicine

Your doctor or nurse have instructions about when to give you your medicine. 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 Gentamicine

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.

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:

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

Very common side effects (may affect more than 1 in 10 people): Feeling sick (vomiting)

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)

How to store Gentamicine

Do not store this medicine above 25°C. It should not be kept in a fridge or freezer.