

## Package leaflet: Information for the user

**Gentamicin 20 mg / mL Solution for injection / infusion  
Gentamicin 40 mg / mL Solution for injection / infusion  
Gentamicin 80 mg / mL Solution for injection / infusion**

Gentamicin

**Read all of this leaflet carefully before you are given this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet

1. What Gentamicin is and what it is used for
2. What you need to know before you are given Gentamicin
3. How Gentamicin is given
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

Gentamicin contains the active substance gentamicin. It belongs to a group of antibiotics called aminoglycosides. This medicine is used to treat severe infections caused by bacteria. This includes:

- infections of the urinary tract (including kidneys or bladder)
- infections in the chest (including lungs), such as hospital-acquired and ventilator-associated pneumonia (HAP and VAP)
- bacterial inflammation of the heart lining (endocarditis)
- infections of the abdomen
- infections of the brain and spinal cord (meningitis caused by bacterial)
- infections of the bones and joints (osteomyelitis and bacterial arthritis)
- management of neutropenic patients with fever that is suspected to be due to a bacterial infection
- infections of the whole body due to the presence of *Listeria monocytogenes* in the blood
- severe infection in newborn babies.
- infections of the blood (bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above)

Note:

Combination treatment is mainly indicated together with a beta-lactam antibiotic (such as, penicillin) or with an antibiotic effective against anaerobic bacteria (bacteria that do not live or grow when oxygen is present) in the following cases: life-threatening infections with an unknown bacteria, mixed anaerobic/aerobic infections, bacterial inflammation of the heart's inner lining (endocarditis), generalised *Pseudomonas* infections, patients with a reduced immune system who lack of certain white blood cells (neutropenia).

### 2. What you need to know before you are given Gentamicin

#### You must not be given Gentamicin

- if you are allergic to gentamicin or any of the other ingredients of this medicine (listed in section 6)

- subcutaneously (beneath the skin), as it is not effective via this route and necrosis (death of body tissue) may occur at the injection site,

### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before you are given *Gentamicin*:

- if you have problems with your kidneys
- if you have liver problems
- if you have diabetes
- if you suffer from deafness or have an ear hearing or balance disorder, a history of ear infections or if you have been treated with medicines that affect hearing in the past
- if you experience severe diarrhoea.

In these cases, you will be given gentamicin only if your doctor regards this treatment as absolutely essential to treat your illness. Your doctor will take special care to adjust your gentamicin dose exactly.

Your doctor will be particularly vigilant if you have a disease affecting your nerve and muscle functions, such as Parkinson's disease or myasthenia gravis, or if you are given a muscle relaxant during surgery, because gentamicin may have a blocking effect on your nerve and muscle functions.

### Children and adolescents

According to the data available, renal and auditory toxicities remain rare in newborn infants and children.

### Monitoring during treatment

To reduce the risk of damage to your kidneys and the nerves in your ears, your doctor will closely follow the recommendations:

- Monitoring of hearing, balance and kidney function before, during and after treatment.
- Selection of a dosage adjusted to your kidney capacity.
- Monitoring of blood gentamicin levels during treatment, if necessary in your case.
- At the same time as gentamicin, avoid administration of other substances that may cause damage to the nerves in the ear or kidneys. If this cannot be avoided, close monitoring of your kidney function is necessary.
- You must tell your doctor immediately if you have severe diarrhoea.
- Additionally, you must ensure adequate hydration and urine production.

### **Other medicines and Gentamicin**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

### **Medicines that may damage the kidneys and hearing**

Tell your doctor if you are receiving or about to receive treatment with medicines that may potentially damage the kidneys or hearing, as there is an increased risk of side effects. These medicines include:

- Amphotericin B (used to treat fungal infections)
- Polymyxin B (antibiotic)
- Ciclosporin (used in organ transplants or for severe skin problems)
- Cisplatin and other organoplatinum compounds (used to treat cancer)
- Other antibiotics of aminoglycoside group, such as tobramycin, streptomycin
- Water tablets or injections (diuretics), such as furosemide
- Tacrolimus (used after organ transplants)
- Cephalothin (antibiotic of cephalosporins group)
- Methoxyflurane (an anaesthetic gas)
- Indometacin (one of a group of medicines called non-steroidal anti-inflammatory agents, used to treat pain and inflammations)
- Anticoagulants (used to thin the blood), such as warfarin and phenindione
- Biphosphonates (used to treat osteoporosis)
- Iodinated contrast media (agent used to facilitate radiographic imaging), antiviral agents (such as the ciclovir group, foscarnet), methotrexate, pentamidine

- Antibiotics of the glycopeptide group, such as vancomycin and teicoplanin
- Neostigmine or pyridostigmine (used to treat muscle weakness)
- Digoxin (used to treat various heart conditions)

#### **Medicines whose effect may be increased by gentamicin**

Also tell your doctor if you are taking the following medicines, as their effect may be increased when used together with gentamicin:

- Botulinum toxin (used to lower the activity of overactive muscles)
- Curare medicines (muscle relaxants).

#### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you are given this medicine.

##### Pregnancy

Gentamicin should only be used during pregnancy for life-threatening indications and when no safer treatment alternatives are available due to the potential danger for the unborn baby. This medicine is not recommended for use in pregnancy unless considered appropriate by your doctor.

##### Breast-feeding

Do not breast-feed during your treatment with gentamicin. Small amounts of gentamicin are excreted in human milk and low concentrations have been found in the serum of breastfed infants. A decision must be made whether to stop breastfeeding or whether to discontinue or not to give gentamicin.

The breast-fed infant may suffer from diarrhoea and thrush in the mouth (fungal infection) whilst the mother is being treated with this medicine.

##### Fertility

It is advised for men to not have children while receiving treatment with this medicine and to use effective contraception during and up to 3 months after this treatment is finished. Talk to your doctor before starting treatment for advice on sperm storage.

#### **Gentamicin contains sodium and sodium metabisulfite**

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

This medicine contains sodium metabisulfite, which may rarely cause severe hypersensitivity reactions and bronchospasm.

### **3. How Gentamicin is given**

Gentamicin is always given to you by a doctor or nurse.

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.

The amount of gentamicin in your blood will be measured regularly to check that the correct blood levels have been achieved. Treatment with gentamicin may cause damage to hearing and also to kidney function. Your doctor will decide, depending on your condition, how long you should receive gentamicin. In some cases, your doctor may carry out blood tests to check your kidney function before and during treatment with gentamicin. Occasionally you may also be asked to take a hearing test to check the medicine is not affecting your hearing.

##### Dosage

The recommended daily dose for children, adolescents and adults with normal kidney function is 3 to 6 mg / kg body weight per day and should preferably be given as a single dose, or else divided into 2 separate doses.

#### *Use in infants*

The daily dose recommended in children aged 1 year and above with normal renal function, is 3 – 6 mg / kg / day as one single dose (preferred) or two divided doses. The recommended daily dose for infants after the first month of life is 4.5 – 7.5 mg / kg body weight per day and should be preferably given as a single dose, or else divided into 2 separate doses. The recommended daily dose for newborn infants is 4 – 7 mg / kg body weight per day. Due to the longer half-life, newborn infants are given the required dose as a single dose.

#### *Use in patients with kidney problems*

If you have kidney problems your daily recommended dose should be reduced and adjusted to kidney function.

#### Method of administration

This medicine is injected into a muscle (intramuscularly) or into a vein (intravenously) after dilution.

#### Duration of use

The duration of use is decided by your doctor.

For common bacterial infectious diseases, the duration of treatment depends on the progression of the disease. Normally, a treatment period of 7 to 14 days is sufficient.

The duration of therapy should preferably not exceed 10 to 14 days.

A course of treatment with *Gentamicin* immediately after a previous course of aminoglycoside treatment should be avoided. You should wait 7 to 14 days before starting treatment with gentamicin.

Please talk to your doctor or nurse if you have the impression that the effect of *Gentamicin* is too strong or too weak.

#### **If you are given more *Gentamicin* than you should**

It is unlikely that your doctor or nurse will give you too much medicine. Your doctor and nurse will monitor your progress and check the medicine you are given. Always ask your doctor or nurse if you are not sure why you are getting a dose of medicine.

#### **If you miss a dose of *Gentamicin***

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 doctor or nurse.

#### **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.

If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

## **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 signs of an allergic reaction, including anaphylactic shock (life-threatening allergic reaction), such as:**

- itching or skin rashes
- swelling of the face, lips or throat
- difficulty in breathing or wheeziness

Other possible side effects:

Common: may affect up to 1 in 10 people

- problems with kidney function

Uncommon: may affect up to 1 in 100 people

- problems with blood clotting
- more or less intense skin redness without papules or blisters

Rare: may affect up to 1 in 1,000 people

- low blood levels of potassium, calcium and magnesium
- increased levels of aldosterone in the blood
- loss of appetite
- weight loss
- damage of peripheral nerves
- loss of feeling
- feeling or being sick
- increased liver enzymes and urea (nitrogen) in the blood (all reversible)
- increased production of saliva
- inflammation of the mouth lining
- skin reddening
- muscle pain
- increased body temperature
- increased serum bilirubin level in the blood

Very rare: may affect up to 1 in 10,000 people

- blood disorders affecting certain blood components and generally detected by blood tests
- decrease in the amount of phosphates in the blood
- confusion, hallucinations, depression
- a collection of brain problems
- seizures (fits)
- neuromuscular block
- dizziness, vertigo, balance disorders, headache
- visual disturbances
- loss of hearing
- inner ear problems, tinnitus
- low blood pressure
- high blood pressure
- erythema multiforme
- hair loss
- muscle wasting (decrease in the mass of the muscle)
- acute kidney failure, raised phosphate levels in the urine and amino acids (known as fanconi syndrome, associated with high doses administered over a long period of time)
- pain at the injection site

Not known: frequency cannot be estimated from the available data

- infection with other gentamicin-resistant germs
- irreversible loss of hearing, deafness
- lethargy (lack of energy and enthusiasm)
- symptoms of bruising, discolouration of skin, small red spots. These could be a sign of purpura.
- 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)
- diarrhoea, with or without blood and/or stomach cramps
- 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).

### **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

**For UK:** Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

**For IE:** HPRA Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie).

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

### **5. How to store Gentamicin**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the outer package and ampoules after EXP. The expiry date refers to the last day of the month.

This medicine does not require any special storage conditions. Do not refrigerate or freeze.

Your doctor or nurse will ensure that your medicine is properly stored.

Gentamicin should be used immediately after opening the ampoule.

Gentamicin is chemically and physically stable for 24 hours at 25°C after dilution in Sodium chloride 0.9 % (9 mg / mL) solution for injection or Glucose 5 % (50 mg / mL) solution for injection. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.

After opening, unused portions must not be stored and should be discarded immediately.

This medicine should be visually inspected prior to use. Only clear solutions, practically free from particles, should be used.

Do not throw away any medicines via wastewater or household waste. Ask your nurse or 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.

**Gentamicin 20 mg / mL:**      Each mL of solution contains 20 mg gentamicin (as gentamicin sulfate).  
Each ampoule of 2 mL solution contains 40 mg gentamicin.

**Gentamicin 40 mg / mL:**      Each mL of solution contains 40 mg gentamicin (as gentamicin sulfate).  
Each ampoule of 2 mL solution contains 80 mg gentamicin.

**Gentamicin 80 mg / mL:** Each mL of solution contains 80 mg gentamicin (as gentamicin sulfate).  
Each ampoule of 2 mL solution contains 160 mg gentamicin.

- The other ingredients are disodium edetate, sodium metabisulfite (E 223), sodium hydroxide 1 N (for pH-adjustment), sulfuric acid 0.5 M (for pH-adjustment), water for injections.

**What Gentamicin looks like and contents of the pack**

Gentamicin solution for injection / infusion is a clear and colourless solution for injection / infusion.  
Each glass ampoule contains 2 mL solution. Pack sizes of 5, 10, 20, 25, 50 or 100 ampoules and pack sizes of 10 (2 x 5), 20 (4 x 5), 25 (5 x 5) or 50 (5 x 10) ampoules are available.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

**Marketing Authorization Holder:** Noridem Enterprises Limited, Evagorou & Makariou, Mitsi Building 3, Office 115, 1065 Nicosia, Cyprus.

**Manufacturer:** DEMO S.A. PHARMACEUTICAL INDUSTRY, 21st Km National Road Athens–Lamia, 14568 Krioneri, Attiki, Greece.

**This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:**

Germany	Gentamicin Noridem 20 mg/ml Injektions-/Infusionslösung Gentamicin Noridem 40 mg/ml Injektions-/Infusionslösung Gentamicin Noridem 80 mg/ml Injektions-/Infusionslösung
Cyprus	OCTORET 20 mg / mL Διάλυμα για ένεση/έγχυση OCTORET 40 mg / mL Διάλυμα για ένεση/έγχυση OCTORET 80 mg / mL Διάλυμα για ένεση/έγχυση
Greece	OCTORET 20 mg / mL Διάλυμα για ένεση/έγχυση OCTORET 40 mg / mL Διάλυμα για ένεση/έγχυση OCTORET 80 mg / mL Διάλυμα για ένεση/έγχυση
Ireland	Gentamicin 20 mg / mL Solution for injection / infusion Gentamicin 40 mg / mL Solution for injection / infusion Gentamicin 80 mg / mL Solution for injection / infusion
Netherlands	Gentamicine Noridem 20 mg/ml oplossing voor injectie/infusie Gentamicine Noridem 40 mg/ml oplossing voor injectie/infusie Gentamicine Noridem 80 mg/ml oplossing voor injectie/infusie
Poland	Gentamicin Noridem Gentamicin Noridem Gentamicin Noridem
United Kingdom (Northern Ireland)	Gentamicin 20 mg / mL Solution for injection / infusion Gentamicin 40 mg / mL Solution for injection / infusion

	Gentamicin 80 mg / mL Solution for injection / infusion
Hungary	Gentamicin Noridem 20 mg/ml oldatos injekció/infúzió Gentamicin Noridem 40 mg/ml oldatos injekció/infúzió Gentamicin Noridem 80 mg/ml oldatos injekció/infúzió

This leaflet was last revised in 10/2022.

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**The following information is intended for healthcare professionals only:**

Please refer to the Summary of Product Characteristics for full prescribing information.

**Posology**

The dose depends on the severity of the clinical picture, the setting, the patient's renal function and the type of infection. Several presentations of gentamicin are available, some of which are more suitable for high doses to be administered intravenously. The dose is expressed in terms of the patient's body weight. The recommended daily dose, adolescents and adults with normal renal function should preferably be given as a single dose, or else divided into 2 separate doses. A dosing frequency of more than twice daily may be adopted for some specific pathogens or some sites of infection as recommended in national and local guidance.

Once daily dosing is not recommended in cases of endocarditis, depending on the responsible pathogens. National and local guidance on treatment with gentamicin and serum level monitoring in endocarditis should be followed.

Dose calculations should be based on ideal body weight.

**Recommendations for dosage**

Posology (adults and adolescents)

Recommended dose:                    3 – 6 mg gentamicin / kg / day

Subsequent doses should be adjusted according to serum concentration levels (see "Monitoring advice") using local guidance or nomograms.

*Dosage in impaired renal function*

Gentamicin is mainly excreted by glomerular filtration. Thus, the dosage for patients with impaired renal function must be adjusted accordingly.

Dose adjustments in patients with renal impairment should also be based on therapeutic drug monitoring. For patients on once daily dose regimens, a prolongation of the dose interval is generally recommended. The initial dose interval should be at least 24 hours and extended according to the degree of renal impairment and the results of serum gentamicin monitoring. Limited data are available in patients with severe renal impairment (creatinine clearance < 30 mL / min) for once daily dose administration.

**Dose adjustment**

Nomograms are available for the calculation of dose or dose interval, which depends on the patient's age, weight and renal function and plasma concentrations. Local guidance should be followed where available. If nomograms or local guidance are not available the following may be used:

For dosage adjustment, there are two possibilities:

- A. Prolongation of the dosing interval while maintaining the same dose (subsequent doses identical to the initial dose).
- B. Reduction of the dose while maintaining the same dosing intervals (subsequent doses smaller than the initial dose).

For patients on once daily dosing, prolonging the dose interval is preferable. For patients on multiple daily dosing, reduction of the dose is preferred.

The following table provides a guideline for reducing the dose whilst maintaining the same dosing intervals (8-hour dosing interval):

Serum creatinine (mg / 100 mL)	Creatinine clearance (mL / min / 1.73 m <sup>2</sup> )	Subsequent doses (percentage of the initial dose)
less than 1.0	more than 100	100
1.1 – 1.3	71 – 100	80
1.4 – 1.6	56 – 70	65
1.7 – 1.9	46 – 55	55
2.0 – 2.2	41 – 45	50
2.3 – 2.5	36 – 40	40
2.6 – 3.0	31 – 35	35
3.1 – 3.5	26 – 30	30
3.6 – 4.0	21 – 25	25
4.1 – 5.1	16 – 20	20
5.2 – 6.6	11 – 15	15
6.7 – 8.0	less than 10	10

It must also be remembered that renal function may change during the course of treatment.

Creatinine clearance should be preferred as a parameter especially in patients with fluctuating plasma creatinine concentrations, such as those observed in severe infections (e.g., sepsis).

If serum creatinine values only are known, creatinine clearance can be estimated using the following formulae:

Men:

$$\text{Body weight in (kg)} \times (140 \text{ minus years of life})$$

$$\text{Cl}_{\text{cr}} = \frac{\text{Body weight in (kg)} \times (140 \text{ minus years of life})}{72 \times \text{serum creatinine (mg / 100 mL)}}$$

or

Men:

$$\text{Body weight in (kg)} \times (140 \text{ minus years of life})$$

$$\text{Cl}_{\text{cr}} = \frac{\text{Body weight in (kg)} \times (140 \text{ minus years of life})}{0.814 \times \text{serum creatinine (\mu mol / L)}}$$

Women:    0.85 x the above value

If serum creatinine values are used for assessing renal function, these values should be taken several times, as correlation to creatinine clearance values exists only when impaired renal function remains the same.

### *Paediatric population*

The daily dose recommended in children aged 1 year and above with normal renal function, is 3 – 6 mg / kg / day as one single dose (preferred) or two divided doses. The recommended daily dose in children after the first month of life is 4.5 – 7.5 mg / kg per day and should be preferably given as a single dose, or else divided into 2 separate doses. The recommended daily dose in newborn infants is 4 – 7 mg / kg body weight per day. Due to the longer half-life, newborn infants are given the required dose as a single dose.

Particular attention must be paid to the preparation (dilution) and amount administered. Any error, however minor, can have a major impact on the serum concentrations obtained.

### *Elderly*

There is some evidence that elderly patients may be more susceptible to aminoglycoside toxicity whether secondary to previous auditory/vestibular impairment or borderline renal dysfunction. Accordingly, therapy should be closely monitored by frequent determination of gentamicin serum levels, assessment of renal function and signs of ototoxicity. If renal function is impaired, the daily recommended dose should be reduced and adjusted to renal function.

### *Hepatic impairment*

In cases of hepatic impairment, gentamicin may be prescribed and no dosage adjustment is necessary.

### *Dosage for haemodialysis patients*

Gentamicin is dialysable. A haemodialysis session lasting 4 – 5 hours or 8 – 12 hours can be expected to reduce concentrations by 50 to 60 % and 70 to 80 %, respectively. After each dialysis session, the patient must be given individual booster doses, based on current gentamicin serum concentrations. Normally, the recommended dose after dialysis is 1 – 1.7 mg / kg body weight.

As haemodialysis patients are usually on anticoagulant therapy, intramuscular injections must not be given in such cases, due to the risk of haematoma formation.

### *Obese patients*

Dose calculations should be based on ideal body weight. In cases of significant obesity gentamicin serum concentrations should be closely monitored.

### Monitoring advice

Regular serum concentration monitoring of gentamicin is recommended for all patients, and especially in the elderly, newborns, obesity and in patients with impaired renal function, as well as in patients with cystic fibrosis. Gentamicin should not be prescribed if serum concentrations cannot be monitored.

There are no universally accepted guidelines for therapeutic drug monitoring of gentamicin. Local monitoring and dose adjustment guidelines should be followed where available. The following is commonly recommended: Pre-dose (“trough level”) monitoring is recommended to ensure that the interval between doses is correct. Trough levels are measured at the end of a dosing interval and should not exceed 1 mg / L for once daily dosing or 2 mg / L for multiple daily dosing. Levels in excess of these indicate the need to extend the interval between doses, not reduction of the dose.

Post-dose (“peak level”) monitoring is recommended to check the adequacy of a dose or to ensure that it is not excessive and likely to cause toxicity. Peak levels should be measured one hour after an intravenous bolus or intramuscular bolus dose, or 30 minutes after the end of an infusion. A plasma concentration < 4 mg / L indicates that the dose is likely to be inadequate and a dose increase should be considered; plasma concentrations > 10 mg / L indicate an increased risk for toxicity, particularly ototoxicity, and a dose reduction should be considered.

Any change in dose should be re-assessed with pre- and post-dose levels to confirm the adequacy of the new dose and the appropriateness of the dose interval.

### Method of administration

For single use only.

For intramuscular, intravenous injection or for intravenous infusion after dilution. The same dosage schedule is recommended for intramuscular and intravenous dosing. Intramuscular administration should be considered when the intravenous route is not possible or less appropriate for the patient

Gentamicin can, if medically indicated, be injected directly into the vein in undiluted form; the injection must be given slowly over 2 – 3 minutes. Rapid, direct intravenous administration may give rise, initially, to potentially neurotoxic concentrations and it is essential that the prescribed dose is administered over the recommended period of time. Alternatively, the prescribed dose should be dissolved in up to 100 mL of sodium chloride 9 mg / mL (0.9 %) solution for injection or glucose 50 mg / mL (5 %) solution for injection and the solution infused over no longer than 20 minutes. The product is intended for single patient use and contains no antimicrobial agent. The injection / infusion must not be administered together with other medicinal substances.

### **Overdose**

Gentamicin has a narrow therapeutic index. In the event of accumulation (e.g. as a result of impaired renal function), renal damage and damage to the vestibulocochlear nerve may occur. Renal damage is correlated to trough levels of more than 4 mg / L.

#### Treatment in case of overdose:

Discontinue medication. There is no specific antidote. In the event of an overdose or toxic reaction, peritoneal dialysis or haemodialysis will lower serum gentamicin levels. In the event of neuromuscular blockade (mostly caused by interactions, q.v. for details), administration of calcium chloride is appropriate; if necessary, artificial ventilation.

### **Incompatibilities**

In general, gentamicin preparations should not be mixed. In particular the following are incompatible in mixed solution with gentamicin preparations: penicillins, cephalosporins, erythromycin, heparins, sodium bicarbonate. \*Dilution in the body will obviate the danger of physical and chemical incompatibility and enable gentamicin to be given concurrently with the medicinal products listed above either as a bolus injection into the drip tubing, with adequate flushing, or at separate sites. In the case of carbenicillin, administration should only be at a separate site.

\*Carbon dioxide may be liberated on addition of the two solutions. Normally this will dissolve in the solution but under some circumstances small bubbles may form.

This also applies to a combination of gentamicin with diazepam, furosemide, or flecainide acetate.