**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**Gentamicin 1 mg/ml solution for infusion**
**Gentamicin 3 mg/ml solution for infusion**

Gentamicin

**Read all of this leaflet carefully before you start using 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.
– If you get any side effects talk to your doctor. This includes any possible side effects not listed in this leaflet.

**What is in this leaflet:**


## 1. What Gentamicin 1 mg/ml or Gentamicin 3 mg/ml is and what it is used for

Gentamicin 1 mg/ml or Gentamicin 3 mg/ml belongs to a group of medicines called antibiotics, that is, they are used to treat severe infections with bacteria that can be killed by the active substance gentamicin.
For the treatment of the diseases listed below, except for complicated infections of kidneys, urinary ducts and bladder, Gentamicin 1 mg/ml or Gentamicin 3 mg/ml should only be used in combination with other antibiotics.

You may receive Gentamicin 1 mg/ml or Gentamicin 3 mg/ml to treat the following diseases:
– Complicated and recurrent infections of kidneys, urinary ducts and bladder
– Infections of lungs and airways occurring during in-patient treatment
– Infections within the belly, including inflammation of the peritoneum
– Infections of skin and soft tissues, including severe burns
– Sepsis (an infection of the entire body), bacteria in the blood
– Inflammation of the inner lining of the heart (to treat infections)
– To treat infections after operations

## 2. What you need to know before you are given Gentamicin 1 mg/ml or Gentamicin 3 mg/ml

**This medicine must not be used**
– if you are allergic to gentamicin, other similar substances or any of the other ingredients of this medicine (listed in section 6).
– if you have myasthenia gravis.

**Warnings and precautions**
Talk to your doctor before you receive this medicine if
– you are pregnant or breastfeeding
– you have impaired kidney function or inner ear deafness
– 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.

Then you will receive gentamicin only if your doctor considers it essential for the treatment of your disease. Your doctor will take special care to adjust your gentamicin dose properly.

Your doctor will exercise particular caution if you have any disease affecting your function of nerves and muscles such as PARKINSON's disease or if you receive a muscle relaxant during an operation, because gentamicin may have a blocking effect on nerve and muscle function.

You should inform your doctor immediately if you experience severe diarrhea.

Your infection might not respond to gentamicin if it did not respond to other aminoglycosides and you may show an allergic reaction to gentamicin if you are already allergic to another aminoglycoside.

There is only limited experience on once daily dosing of gentamicin in elderly patients.

In order to reduce the risk of damage to your ear nerve and your kidneys your doctor will carefully consider the following:
– Monitoring of hearing, balance, and renal function before, during and after treatment.
– Dosage strictly according to your kidney performance.
– If you have impaired kidney function, antibiotics additionally administered directly to the site of infection will be taken into account for the total dosage.
– Monitoring of serum gentamicin concentrations during therapy if the particulars of your case demand.
– If you already have ear nerve damage (hearing or balance function impairment), or where treatment is long-term, additional monitoring of the balance function and hearing is required.
– If possible, you will receive the therapy with gentamicin not longer than 10 –14 days (usually 7 – 10 days).
– There should be sufficient time, 7 – 14 days, between individual treatments with gentamicin or other closely related antibiotics.
– Avoiding administration of other substances with possibly damaging effects on the ear nerve or the kidneys together with gentamicin. If this is unavoidable, particular careful monitoring of your kidney function is necessary.
– Your body fluid level and urine production should be in the normal range.

**Using other medicines and Gentamicin 1 mg/ml or Gentamicin 3 mg/ml**
Tell your doctor if you are taking, have recently taken or might take any other medicines.

The following medicinal products should be paid attention to:

*Ether, muscle relaxants*
The blocking of nerve and muscle function by aminoglycosides is enhanced by ether and muscle relaxants. Therefore you will be monitored with particular care while you receive such substances.

*Methoxyflurane anaesthesia*
The anaesthetist should know if you have received or are receiving aminoglycosides before performing anaesthesia with methoxyflurane (an anaesthetic gas) and avoid to use this agent if ever possible, because of an increased risk of kidney damage

*Other medicinal products with possibly damaging effects on ear nerve and kidneys*
You will be monitored very carefully if you receive gentamicin before, during or after treatment with: medicinal products that contain the following substances:
– amphotericin B (against fungal infections),
– colistin (for gut decontamination),
– ciclosporin (for suppression of undesirable immune reactions),
– cisplatin (anti-cancer agent),
– vancomycin, streptomycin, viomycin, carbenicillin, other aminoglycosides, cephalosporins (antibiotics)

You will be also monitored very carefully if you receive medicines to increase the urine flow containing e.g. ethacrynic acid and furosemide.

**Pregnancy and breast-feeding**
*Pregnancy*
If you are pregnant or breast-feeding, think you may be pregnant or a planning to have a baby, ask your doctor for advice before taking this medicine. This medicine should not be used during pregnancy unless it is absolutely necessary.

*Breast-feeding*
Tell your doctor if you are breast-feeding. Your doctor will carefully consider whether nursing or gentamicin therapy should be discontinued.

**Driving and using machines**
Caution is advised when driving and using machines in view of the possible undesired effects such as dizziness and vertigo.

**Gentamicin 1 mg/ml and Gentamicin 3 mg/ml contain sodium**

[Gentamicin 1 mg/ml]
This medicine contains 283 mg sodium (main component of cooking/table salt) in each bottle.
This is equivalent to 14.2 % of the recommended maximum daily dietary intake of sodium for an adult.

[Gentamicin 3mg/ml]

This medicine contains 283/ 425 mg of sodium (main component of cooking/table salt) in each 80/120 ml bottle.
This is equivalent to 14.2 %/ 21.3 % of the recommended maximum daily dietary intake of sodium for an adult.

## 3. How Gentamicin 1 mg/ml or Gentamicin 3 mg/ml is given to you

**Dosage in patients with normal renal function**

**Adults/Adolescents**

The daily dose recommended in adolescents and adults with normal renal function, is 3 – 6 mg/kg body weight per day as 1 (preferred) up to 2 single doses.

Usually you will receive treatment with gentamicin not longer than for 7 – 10 days, only in cases of severe and complicated infections treatment can exceed 10 days.

Your blood levels of the gentamicin will be carefully monitored by examining blood samples taken at the end of a dosage interval and immediately after the end of the infusion, mainly in order to control your kidney function. Your dose will carefully be adjusted in order to avoid kidney damage.

**Children** (2 until 12 years of age)

The daily dose in newborns is 4 – 7 mg/kg body weight per day. Newborns are given the required daily dose in one single dose.
The daily dose in suckling infants after the first month of life is 4.5 – 7.5 mg/kg body weight per day as 1 (preferred) up to 2 single doses.
The daily dose recommended in older children with normal renal function is 3 – 6 mg/kg body weight per day as 1 (preferred) up to 2 single doses.

**Dosage in patients with kidney function impairment**
If you have kidney function impairment you will be monitored in order to adequately adjust the gentamicin concentrations in the blood, either by lowering the dose or by extending the time between individual doses. Your doctor knows how to adjust the dosage schedule in such a case.

**Dosage in patients under treatment with kidney dialysis**
In this case your dose will be carefully adjusted according to the gentamicin level in your blood.

**Elderly patients** may require lower maintenance doses than younger adults in order to obtain sufficient gentamicin levels in blood.

In **very overweight patients** the starting dose should be based on ideal body weight plus 40 per cent of weight excess.

In patients with **liver function impairment** no dose adjustment is required.

**If you receive more Gentamicin 1 mg/ml or Gentamicin 3 mg/ml than you should**
In the event of accumulation (e.g. as a result of impaired kidney function), further kidney damage and damage to the ear nerve may occur.

Treatment in the event of overdose
At first treatment will be stopped. There is no specific antidote. Gentamicin can be removed from the blood by kidney dialysis. For treatment of blockade of nerve and muscle function calcium chloride may be given and artificial respiration if necessary.
If you have any further questions on the use of this medicine, ask your doctor or nurse.

**Method of administration**
Gentamicin 1 mg/ml solution for infusion or Gentamicin 3 mg/ml solution for infusion is administered by a drip directly into a vein (intravenous infusion). The solution for infusion in the polyethylene bottle are administered over a period of 30 – 60 minutes.

Gentamicin 1 mg/ml solution for infusion or Gentamicin 3 mg/ml solution for infusion should not be administered by injection into the muscle or vein (intramuscular or intravenous injection).

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Under certain conditions gentamicin shows toxic effects on ear nerve and kidneys. Kidney impairment is commonly observed in patients treated with gentamicin and will usually resolve after withdrawal of the drug. In most cases kidney toxicity is associated with an excessively high dosage or long-lasting treatment, already existing kidney abnormalities, or is associated with other substances also having a toxic effect on kidneys. Additional risk factors for kidney toxicity are advanced age, low blood pressure, decreased blood volume or shock, or existing liver disease. Risk factors for toxic effects on the ear nerve are existing liver or hearing impairment, bacteria in the blood, and fever.

The following side effects, which may occur very rarely, that is, in less than 1 of 10 000 treated patients, may be serious and demand immediate treatment:
– severe acute hypersensitivity (allergic) reactions
– acute kidney failure

Skin rash, itching and difficulty in breathing can by signs of acute hypersensitivity.
Decreased amount of urine or complete urination stop (oliguria, anuria), excessive urination at night,

and generalized swelling (fluid retention) are signs of acute kidney failure.

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| **Infections and infestations:** | |
| Very rare (may affect up to 1 in 10 000 people): | Infection with other, gentamicin-resistant germs, large bowel inflammation (may usually be due to other antibiotics) |
| **Blood and lymphatic system disorders:** | |
| Uncommon (may affect up to 1 in 100 people): | Abnormal blood composition |
| Very rare( may affect up to 1 in 10 000 people): | Abnormally low counts of different blood cell types, increased count of eosinophils (a certain group of white blood cells) |
| **Immune system disorders – allergic reactions:** | |
| Very rare (may affect up to 1 in 10 000 people): | Drug fever, severe acute hypersensitivity reactions |
| **Metabolism and nutrition disorders:** | |
| Rare (may affect up to 1 in 1 000 people): | Low blood levels of potassium, calcium and magnesium (associated with high doses given over long time), loss of appetite, weight loss |
| Very rare (may affect up to 1 in 10 000 people): | Low blood levels of phosphate (associated with high doses given over long time) |
| **Psychiatric disorders:** | |
| Very rare (may affect up to 1 in 10 000 people): | Confusion, hallucinations, mental depression |
| **Nervous system disorders:** | |
| Rare (may affect up to 1 in 1 000 people): | Damage of peripheral nerves, impairment or loss of feeling |
| Very rare (may affect up to 1 in 10 000 people): | Organic brain disease, convulsions, blockage of nerve and muscle function, dizziness, balance disorder, headache |
| **Eye disorders:** | |
| Very rare (may affect up to 1 in 10 000 people): | Impairment of vision |
| **Ear and labyrinth disorders:** | |
| Very rare (may affect up to 1 in 10 000 people): | Damage on the ear nerve, hearing loss, Meniére's disease, ringing/ roaring in the ears, vertigo |
| Frequency Unknown (frequency cannot be estimated from the available data): | Irreversible hearing loss, deafness |
| **Blood vessel disorders:** | |
| Very rare (may affect up to 1 in 10 000 people): | Decreased blood pressure, increased blood pressure |

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| **Stomach and gut disorders:** | |
| Rare (may affect up to 1 in 1 000 people): | Vomiting, sickness, increased salivation, inflammation in the mouth, |
| Liver and bile disorders: | |
| Rare (may affect up to 1 in 1 000 people): | increased levels of liver enzymes and blood bilirubin, (all reversible) |
| **Skin and subcutaneous tissue disorders:** | |
| Uncommon (may affect up to 1 in 100 people): | Allergic skin rash, itching |
| Rare (may affect up to 1 in 1 000 people): | Skin reddening |
| Very rare (may affect up to 1 in 10 000 people): | Hair loss, Severe allergic reaction of the skin an mucous membranes accompanied by blistering and reddening of the skin (Erythema multiforme), which might in very severe cases affect inner organs and might be life threatening (Stevens-Johnson syndrome, toxic epidermal necrolysis) |
| **Disorders of muscles, skeleton, and connective tissue:** | |
| Rare (may affect up to 1 in 1 000 people): | Muscle pain (myalgia) |
| Very rare (may affect up to 1 in 10 000 people): | Tremor of muscles (causing difficulty in standing) |
| **Kidney and urinary disorders:** | |
| Common (may affect up to 1 in 10 people): | Kidney function impairment (usually resolving after stop of treatment) |
| Rare (may affect up to 1 in 1 000 people): | increased levels of blood urea (reversible) |
| Very rare (may affect up to 1 in 10 000 people): | Acute kidney failure, High urine levels of phosphate and amino acids (so called Fanconi-like syndrome, associated with high doses given over long time) |
| **General disorders and administration site conditions:** | |
| Rare (may affect up to 1 in 1,000 people): | Increased body temperature |
| Very rare (may affect up to 1 in 10 000 people): | Pain at injection site |
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**Reporting of side effects**

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom:
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

Ireland:
HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie

## 5. How to store Gentamicin 1 mg/ml or Gentamicin 3 mg/ml

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 bottle and the outer carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

The solution should be used immediately after first opening.
This medicinal product is for single use only. The solution should only be used if the solution is clear, colourless and free from particles.
Any unused solution should be discarded.

## 6. Contents of the pack and further information

**What Gentamicin 1 mg/ml or Gentamicin 3 mg/ml contains**

– The active substance is Gentamicin

1 ml of Gentamicin 1 mg/ml solution for infusion contains 1 mg of gentamicin, as gentamicin sulphate.

1 bottle of 80 ml contains 80 mg of gentamicin.

1 ml of Gentamicin 3 mg/ml solution for infusion contains 3 mg of gentamicin, as gentamicin sulphate.

1 bottle of 80 ml contains 240 mg of gentamicin.
1 bottle of 120 ml contains 360 mg of gentamicin.

– The other ingredients are
Disodium edetate (3 mg/ml solution), sodium chloride, water for injections

**What Gentamicin 1 mg/ml and Gentamicin 3 mg/ml looks like and contents of the pack**
Gentamicin 1 mg/ml and Gentamicin 3 mg/ml are solutions for infusion; i.e. they are administered as a drip through a small tube or cannula placed in a vein.
They are clear colourless solutions.

Gentamicin 1 mg/ml solution for infusion comes in polyethylene bottles of 80 ml.
It is supplied in packs of 10 or 20 bottles.

Gentamicin 3 mg/ml solution for infusion comes in polyethylene bottles of 80 and 120 ml.
Both are supplied in packs of 10 or 20 bottles.

Not all package sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

B. Braun Melsungen AG
Carl-Braun Straße 1
34212 Melsungen, Germany

Postal address:
34209 Melsungen, Germany

Phone: +49-5661-71-0
Fax: +49-5661-71-4567

B. Braun Medical S. A.
Carretera de Terrassa 121
08191 Rubí (Barcelona), Spain

This medicinal product is authorised in the Member States of the EEA under the following names:

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| Austria - | Gentamicin B. Braun 1 mg/ml Infusionslösung<br>Gentamicin B. Braun 3 mg/ml Infusionslösung |
| Belgium - | Gentamycine B. Braun 1 mg/ml Solution pour perfusion / Infusionslösung / Oplossing voor infusie<br>Gentamycine B. Braun 3 mg/ml Solution pour perfusion / Infusionslösung / Oplossing voor infusie |
| Czech Republic - | Gentamicin B. Braun 1 mg/ml<br>Gentamicin B. Braun 3 mg/ml |
| Denmark - | Gentamicin B. Braun |
| Germany | Gentamicin B. Braun 1 mg/ml Infusionslösung<br>Gentamicin B. Braun 3 mg/ml Infusionslösung |
| Finland - | Gentamicin B. Braun 1 mg/ml<br>Gentamicin B. Braun 3 mg/ml |
| Iceland: | Gentamicin B. Braun 1 mg/ml innrennslislyf, lausn<br>Gentamicin B. Braun 3 mg/ml innrennslislyf, lausn |
| Ireland - | Gentamicin 1 mg/ml solution for infusion<br>Gentamicin 3 mg/ml solution for infusion |
| Italy - | Gentamicina B. Braun 1 mg/ml soluzione per infusione<br>Gentamicina B. Braun 3 mg/ml soluzione per infusione |
| Luxembourg - | Gentamicin B. Braun 1 mg/ml Infusionslösung<br>Gentamicin B. Braun 3 mg/ml Infusionslösung |
| Norway - | Gentamicin B. Braun 1 mg/ml infusjonsvæske, oppløsning<br>Gentamicin B. Braun 3 mg/ml infusjonsvæske, oppløsning |
| Poland - | Gentamicin B. Braun |
| Portugal - | Gentamicina B. Braun 1 mg/ml Solução para perfusão<br>Gentamicina B. Braun 3 mg/ml Solução para perfusão |
| Slovenia - | Gentamicin B. Braun 1 mg/ml raztopina za infundiranje<br>Gentamicin B. Braun 3 mg/ml raztopina za infundiranje |
| Slovakia - | Gentamicin B. Braun 1 mg/ml infúzny roztok<br>Gentamicin B. Braun 3 mg/ml infúzny roztok |
| United Kingdom - | Gentamicin 1 mg/ml solution for infusion<br>Gentamicin 3 mg/ml solution for infusion |

**This leaflet was last revised in 10/2020**.

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The following information is intended for medical or healthcare professionals only:

Gentamicin 1 mg/ml solution for infusion and Gentamicin 3 mg/ml solution for infusion is a ready-to-use formulation and should not be diluted prior to administration.

On no account may aminoglycosides be mixed in an infusion solution with beta-lactam antibiotics (e.g. penicillins, cephalosporins), erythromycin, or lipiphysan as this may cause physico-chemical inactivation. This also applies to a combination of gentamicin with diazepam, furosemide, flecainide acetate or heparin sodium.

The following active substances or solution for reconstitution/dilution should not be administered simultaneously:

Gentamicin is incompatible with amphotericin B, cephalothin sodium, nitrofurantoin sodium, sulfadiazine sodium and tetracyclines.

Addition of gentamicin to solutions containing bicarbonate may lead to the release of carbon dioxide.

From the 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.'

The solution should be administered with sterile equipment using an aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.

For single use only.
Unused solution should be discarded.
The solution is to be inspected visually for particulate matter and discoloration prior to administration.
The solution should only be used if the solution is clear and free from particles