10 mm

FRONT
148 × 590

Package leaflet: Information for the patient

Gentamicin 10 mg/ml
Gentamicin 40 mg/ml

solution for injection/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.
- 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. 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

Gentamicin 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.

Gentamicin should only be used in combination with other antibiotics except for complicated infections of the kidneys, urinary tract and bladder.

You may receive Gentamicin to treat the following diseases:

- Complicated infections of the urinary tract
- Infections and inflammation within the belly
- Infections of lungs and airways occurring during hospital treatment
- Infections of lungs from cystic fibrosis
- Inflammation of the inner lining of the heart (to treat infections)
- Infections of the skin related to severe burns
- Serious infections with bacteria in the blood

2. What you need to know before you use Gentamicin

Do not use Gentamicin:

- if you are allergic to gentamicin or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from myasthenia gravis (a disease that causes muscle fatigue).

Warnings and precautions

Talk to your doctor before using Gentamicin.

Gentamicin solution for injection/infusion must not be used via the inhalation route.

Your doctor needs to know if:

- you are pregnant or breast-feeding;
- you have impaired kidney function;
- you suffer from deafness.

In such cases, you will be given gentamicin only if your doctor thinks that this treatment is absolutely necessary 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 if you are given a muscle relaxant during surgery, because gentamicin may have a blocking effect on your nerve and muscle functions.

If you 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 or pharmacist before you take 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.

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

- Monitoring of hearing including ringing/whistling noises (tinnitus), balance including dizziness and vertigo and kidney function before, during and after treatment.
- If your ear nerve is already damaged, or if you are undergoing a long-term treatment with Gentamicin, you may be additionally examined for hearing and balance.
- Selection of a dosage adjusted to your kidney capacity.
- Monitoring of your 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.

If any of the following symptoms of ototoxicity appear you should immediately inform your doctor

- Tinnitus or ringing in the ears.
- Bilateral or unilateral hearing loss.
- Dizziness.
- Incoordination of movements.
- Unsteadiness of gait.
- Oscillating or bouncing vision.

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

Children and adolescents

According to the data available, toxicities of the kidney and ear nerve remain rare in newborns and children.

Other medicines and Gentamicin

Tell your doctor if you are using, have recently used or might use any other medicines.

Your doctor should take special attention if you are taking the following medicines:

Other aminoglycosides administered at the same time as gentamicin

Increased risk of kidney and ear damage.

Loop diuretics (drugs used for treatment of high blood pressure)

Increased risks of kidney and ear damage. This combination is possible if you are monitored for the amount of fluid in your body, kidney and ear function, and the amount of antibiotic in your blood.

Drugs causing the toxicity of the ear

If you are administered drugs causing ear damage together with Gentamicin, you may be at increased risk of damage to your ear nerve. If such a combination is necessary, you will be monitored for hearing function.

Medicines that may cause the ear damage include antibiotics such as vancomycin, teicoplanin and other aminoglycosides, organoplatinum compounds (used to treat cancer) and loop diuretics (used for treatment of high blood pressure, such as furosemide).

Drugs causing toxicity of the kidneys

If you are administered drugs causing kidney damage together with Gentamicin, you may be at increased risk of damage to your kidneys. If such a combination is necessary, you will be monitored for kidney function. In particular, medicines that may cause kidney damage include iodinated contrast media (contrast agent for radiographic procedures), aminoglycosides (antibiotics), organoplatinum compounds (used to treat cancer), high-dose methotrexate (used to treat cancer, arthritis and psoriasis), certain agents used for treatment of virus infections (e.g. the "–ciclovir" group, foscarnet), amphotericin B (used to treat fungal infections), pentamidine (antimicrobial medicine), ciclosporin or tacrolimus (medicines that reduce the activity of the body's immune system).

Gentamicin is usually contraindicated in patients treated with cisplatine (used to treat cancer) and platinum compounds, as the kidney damage caused by gentamicin may be increased for several weeks after the administration of cisplatine or platinum therapy.

Polymyxin B

Administration of polymyxin B (antibiotic) together with Gentamicin may cause kidney damage. If the combination cannot be avoided, you will be closely monitored for kidney function.

Muscle relaxants during anesthesia

If you are administered as a part of your anesthesia a certain type of muscle-relaxing drug together with Gentamicin, the effect of the muscle relaxant may be stronger than usual. You will be monitored for the degree of your muscle relaxation at the end of anesthesia.

Contraceptives

In rare cases, some antibiotics are supposedly capable of diminishing the effect of contraceptive pills.

Botulinum toxin

Use of gentamicin must be avoided during treatment with botulinum toxin (used to treat muscle stiffness, migraine, overactive bladder and in cosmetic procedures). Use another antibiotic.

Pregnancy and breast-feeding

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

Pregnancy

Unless advised by your doctor, this medicine is not recommended for use during pregnancy.

If you find out that you are pregnant during treatment, consult your doctor as soon as possible: as only he/she can adjust the treatment to your condition.

In the case of exposure during pregnancy, it is advisable to assess the newborn baby's hearing and kidney function.

Breast-feeding

Breast-feeding is not recommended during treatment with gentamicin.

Your doctor will consider carefully whether breast-feeding or gentamicin treatment should be stopped.

Driving and using machines

Precautions must be taken when driving or using machines due to side effects such as dizziness and vertigo.

Gentamicin contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 2 ml that is to say essentially 'sodium-free'.

3. How to use Gentamicin

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Gentamicin solution for injection/infusion must not be administered via the inhalation route.

Individual dose will be determined by your doctor according to your body weight and kidney function.

Daily doses of gentamicin are administered in a single injection. In certain situations the dose may be given as two injections over 24 hours. The treatment course may be complete after two to three days or continued for a maximum of seven days, according to test results.

The adult dose is 3-6 mg/kg/day, depending on the duration of the course, type and severity of the bacterial infection.

Your doctor will monitor your blood level of Gentamicin during treatment, especially if you are elderly, newborn, obese, have renal impairment or suffer from cystic fibrosis (a serious disease affecting several organs for example the lungs and gastrointestinal system).

Use in children and adolescents

- Children and adolescent with normal kidney function will be given their daily dose 3-6 mg/kg administered in one injection. The dose may be divided into two injections over 24 hours in certain situations.

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

To avoid adverse events, continuous monitoring (before, during and after) of renal function (serum creatinin, creatinin clearance), control of function of vestibule and cochlea as well as hepatic and laboratory parameters is recommended.

Therapeutic monitoring

Regular serum concentration monitoring of gentamicin is recommended for all patients, and especially the elderly, newborns, obese patients, patients with impaired renal function and 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.

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.

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.

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- Infants after their first month of life: 4,5-7,5 mg/kg daily administered in one injection. The dose may be divided into two injections over 24 hours in certain situations.
- Neonates and pre-term infants (aged 0-4 weeks old): 4-7 mg/kg daily administered in one injection.

The accuracy of dosing in children is very important as even minor errors may be significant. There is no dose recommendation for children with impaired kidney function.

For patients with impaired kidney function

First injection: 3 to 6 mg/kg/day. Other injections will be given either in the same dose or adjusted according to your gentamicin blood levels.

If you are undergoing dialysis, you will be administered Gentamicin 2 to 4 hours before the dialysis in order to reduce the potential toxicity.

For elderly patients

Your treatment with Gentamicin will be determined according to your kidney function and signs of toxicity.

For obese patients

You will be administered your dose according to your lean body weight.

For patients with impaired liver function

No dosage adjustment is necessary.

Method of administration

Infusion over 20-30 minutes into the vein in diluted form or injection directly into the vein over no less than 3 minutes or administration into the muscle.

If you use more Gentamicin than you should

Contact your doctor if you think you have been given too much Gentamicin. In case of overdose, dialysis may be recommended. Overdose of gentamicin is serious and may cause hearing and kidney damage.

If you forget to use Gentamicin

Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

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

The following very rare side effects may be life-threatening and demand immediate medical attention:

- 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)

Very rare side effects (less than 1 in 10,000 people will probably be affected):

- Acute kidney failure:
  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.
- Serious allergic reaction of the skin, mouth and throat with blistering and redness of the skin (erythema multiforme) which in severe cases can affect the internal organs (Stevens-Johnson syndrome, toxic epidermal necrolysis), skin detachment (toxic epidermal necrolysis, or Lyell's syndrome).
- Disorders of the brain and nerves:
  Swelling of the brain (encephalopathy), muscle paralysis (neuromuscular block), seizures.

Other side effects:

Common side effects (less than 1 in 10 people and more than 1 in 100 people will probably be affected)

- Impaired kidney function

Uncommon side effects (less than 1 in 100 people and more than 1 in 1,000 people will probably be affected)

- Impaired blood clotting
- More or less intense skin redness without papules or blisters

Rare side effects (less than 1 in 1,000 people and more than 1 in 10,000 people will probably be affected)

- Low blood levels of potassium, calcium and magnesium
- Disorder of the kidneys
- Loss of appetite
- Weight loss
- Disorder of the nerves
- Abnormal sensory perception
- Vomiting, nausea
- Increased liver enzymes and urea in the blood (all reversible)
- Increased salivation
- Inflammation of the mouth lining
- Skin reddening
- Muscle pain
- Increased body temperature

Very rare side effects (less than 1 in 10,000 people will probably be affected)

- Infection with gentamicin-resistant germs
- Diarrhoea, with or without blood and/or stomach cramps
- Very severe inflammation of the large intestine
- Blood disorders affecting certain blood components and generally detected by blood tests
- Anaemia
- Blood disorders
- Confusion, hallucinations, depression
- Dizziness, vertigo, balance disorders, headache
- Visual disturbances
- Loss of hearing
- Inner ear problems, ringing in the ear
- Changes in blood pressure
- Hair loss
- Muscle tremor
- Abnormal changes to urine (so called Fanconi-like syndrome, associated with high doses given over a long time)
- Pain at the injection site

Unknown (frequency cannot be estimated from the available data)

- Irreversible loss of hearing, deafness. Symptoms which may be sign of hearing damage include: temporary loss of hearing, ringing in the ears, dizziness, balance and visual disruptions

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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

Store this medicine below 30°C. Do not freeze.

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

After opening: the product must be used immediately.

Do not use the medicine if it is visibly deteriorated and return it to the pharmacy.

Do not throw away any medicines via wastewater or household waste. 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.
- The other ingredients are: disodium edetate, sodium chloride, sulfuric acid and water for injections. Each ampoule of 2 ml contains either 20.0 mg or 80.0 mg of gentamicin as gentamicin sulfate.

What Gentamicin looks like and contents of the pack

This medicine is presented as a clear, colourless solution for injection/infusion.

Gentamicin 10 mg/ml is supplied in glass ampoules in packs of 5.

Gentamicin 40 mg/ml is supplied in glass ampoules in packs of 1, 5, 10 or 25.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
PANPHARMA
Z.I. du Clairay
35133 Luitré
France

Manufacturer
PANPHARMA GmbH
Bunsenstrasse 4
22946 Trittau
Germany

This leaflet was last revised in 08/2024.

folding line

Instructions for administration and dilution:

After opening; the product must be used immediately.

Gentamicin when given intravenously should be injected directly into a vein or into the drip set tubing over no less than three minutes. If administered by infusion, this should be over 20 – 30 minutes and in no greater volume of fluid than 100 ml. Longer infusion times of up to 60 minutes may be used, in particular for a once daily dosing regimen. Once daily dosing should only be administered through the intravenous route.

For the intravenous route, the amount of gentamicin to be administered is to be diluted in up to 100 ml of one the following fluids:

- glucose 5%
- sodium chloride 0.9%

Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C when diluted with the infusion fluids listed above.

Chemical and physical in-use stability has also been demonstrated for 3 hours at 25°C, after 24 hours at 2-8°C when diluted with the infusion fluids listed above.

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 reconstitution and dilution have taken place in controlled validated aseptic conditions.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Incompatibilities:

This medicinal product must not be mixed with other medicinal products except those listed under 'Instructions for administration and dilution'.

PANPHARMA

22.08.2024

MOCK-UP TYPE

- [ ] box
- [x] leaflet
- [ ] label
- [ ] bag
- [ ] overwrap
- [ ] blisters
- [ ] box label
- [ ] other:

PRODUCT	*Gentamicine*
Country	*UK*
Dimensions	*148 × 590*
ADC code	*PIM-MOCKUP-2024-0363*
Visa	*RTo*

PANTONES

293u

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- Muscle pain
- Increased body temperature

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Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Incompatibilities:

This medicinal product must not be mixed with other medicinal products except those listed under 'Instructions for administration and dilution'.

The accuracy of dosing in children is very important as even minor errors may be significant. There is no dose recommendation for children with impaired kidney function.

For patients with impaired kidney function

First injection: 3 to 6 mg/kg/day. Other injections will be given either in the same dose or adjusted according to your gentamicin blood levels.

If you are undergoing dialysis, you will be administered Gentamicin 2 to 4 hours before the dialysis in order to reduce the potential toxicity.

For elderly patients

Your treatment with Gentamicin will be determined according to your kidney function and signs of toxicity.

For obese patients

You will be administered your dose according to your lean body weight.

For patients with impaired liver function

No dosage adjustment is necessary.

Method of administration

Infusion over 20-30 minutes into the vein in diluted form or injection directly into the vein over no less than 3 minutes or administration into the muscle.

If you use more Gentamicin than you should

Contact your doctor if you think you have been given too much Gentamicin. In case of overdose, dialysis may be recommended. Overdose of gentamicin is serious and may cause hearing and kidney damage.

If you forget to use Gentamicin

Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

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

The following very rare side effects may be life-threatening and demand immediate medical attention:
- 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)

Very rare side effects (less than 1 in 10,000 people will probably be affected):
- Acute kidney failure:
  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.
- Serious allergic reaction of the skin, mouth and throat with blistering and redness of the skin (erythema multiforme) which in severe cases can affect the internal organs (Stevens-Johnson syndrome, toxic epidermal necrolysis), skin detachment (toxic epidermal necrolysis, or Lyell's syndrome).
- Disorders of the brain and nerves: Swelling of the brain (encephalopathy), muscle paralysis (neuromuscular block), seizures.

Other side effects:

Common side effects (less than 1 in 10 people and more than 1 in 100 people will probably be affected)
- Impaired kidney function

Uncommon side effects (less than 1 in 100 people and more than 1 in 1,000 people will probably be affected)
- Impaired blood clotting
- More or less intense skin redness without papules or blisters

Rare side effects (less than 1 in 1,000 people and more than 1 in 10,000 people will probably be affected)
- Low blood levels of potassium, calcium and magnesium
- Disorder of the kidneys
- Loss of appetite
- Weight loss
- Disorder of the nerves
- Abnormal sensory perception
- Vomiting, nausea

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

To avoid adverse events, continuous monitoring (before, during and after) of renal function (serum creatinin, creatinin clearance), control of function of vestibule and cochlea as well as hepatic and laboratory parameters is recommended.

Therapeutic monitoring

Regular serum concentration monitoring of gentamicin is recommended for all patients, and especially the elderly, newborns, obese patients, patients with impaired renal function and 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.

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.

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.

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Other aminoglycosides administered at the same time as gentamicin

Increased risk of kidney and ear damage.

Loop diuretics (drugs used for treatment of high blood pressure)

Increased risks of kidney and ear damage. This combination is possible if you are monitored for the amount of fluid in your body, kidney and ear function, and the amount of antibiotic in your blood.

Drugs causing the toxicity of the ear

If you are administered drugs causing ear damage together with Gentamicin, you may be at increased risk of damage to your ear nerve. If such a combination is necessary, you will be monitored for hearing function.

Medicines that may cause the ear damage include antibiotics such as vancomycin, teicoplanin and other aminoglycosides, organoplatinum compounds (used to treat cancer) and loop diuretics (used for treatment of high blood pressure, such as furosemide).

Drugs causing toxicity of the kidneys

If you are administered drugs causing kidney damage together with Gentamicin, you may be at increased risk of damage to your kidneys. If such a combination is necessary, you will be monitored for kidney function. In particular, medicines that may cause kidney damage include iodinated contrast media (contrast agent for radiographic procedures), aminoglycosides (antibiotics), organoplatinum compounds (used to treat cancer), high-dose methotrexate (used to treat cancer, arthritis and psoriasis), certain agents used for treatment of virus infections (e.g. the "–ciclovir" group, foscarnet), amphotericin B (used to treat fungal infections), pentamidine (antimicrobial medicine), ciclosporin or tacrolimus (medicines that reduce the activity of the body's immune system).

Gentamicin is usually contraindicated in patients treated with cisplatine (used to treat cancer) and platinum compounds, as the kidney damage caused by gentamicin may be increased for several weeks after the administration of cisplatine or platinum therapy.

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Administration of polymyxin B (antibiotic) together with Gentamicin may cause kidney damage. If the combination cannot be avoided, you will be closely monitored for kidney function.

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In rare cases, some antibiotics are supposedly capable of diminishing the effect of contraceptive pills.

Botulinum toxin

Use of gentamicin must be avoided during treatment with botulinum toxin (used to treat muscle stiffness, migraine, overactive bladder and in cosmetic procedures). Use another antibiotic.

Pregnancy and breast-feeding

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

Pregnancy

Unless advised by your doctor, this medicine is not recommended for use during pregnancy.

If you find out that you are pregnant during treatment, consult your doctor as soon as possible: as only he/she can adjust the treatment to your condition.

In the case of exposure during pregnancy, it is advisable to assess the newborn baby's hearing and kidney function.

Breast-feeding

Breast-feeding is not recommended during treatment with gentamicin.

Your doctor will consider carefully whether breast-feeding or gentamicin treatment should be stopped.

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Your doctor will monitor your blood level of Gentamicin during treatment, especially if you are elderly, newborn, obese, have renal impairment or suffer from cystic fibrosis (a serious disease affecting several organs for example the lungs and gastrointestinal system).

Use in children and adolescents

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Package leaflet: Information for the patient

Gentamicin 10 mg/ml
Gentamicin 40 mg/ml
solution for injection/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.
- 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. 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

Gentamicin 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.

Gentamicin should only be used in combination with other antibiotics except for complicated infections of the kidneys, urinary tract and bladder.

You may receive Gentamicin to treat the following diseases:

- Complicated infections of the urinary tract
- Infections and inflammation within the belly
- Infections of lungs and airways occurring during hospital treatment
- Infections of lungs from cystic fibrosis
- Inflammation of the inner lining of the heart (to treat infections)
- Infections of the skin related to severe burns
- Serious infections with bacteria in the blood

2. What you need to know before you use Gentamicin

Do not use Gentamicin:

- if you are allergic to gentamicin or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from myasthenia gravis (a disease that causes muscle fatigue).

Warnings and precautions

Talk to your doctor before using Gentamicin.

Gentamicin solution for injection/infusion must not be used via the inhalation route.

Your doctor needs to know if:

- you are pregnant or breast-feeding;
- you have impaired kidney function;
- you suffer from deafness.

In such cases, you will be given gentamicin only if your doctor thinks that this treatment is absolutely necessary 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 if you are given a muscle relaxant during surgery, because gentamicin may have a blocking effect on your nerve and muscle functions.

If you 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 or pharmacist before you take 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.

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

- Monitoring of hearing including ringing/whistling noises (tinnitus), balance including dizziness and vertigo and kidney function before, during and after treatment.
- If your ear nerve is already damaged, or if you are undergoing a long-term treatment with Gentamicin, you may be additionally examined for hearing and balance.
- Selection of a dosage adjusted to your kidney capacity.
- Monitoring of your 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.

If any of the following symptoms of ototoxicity appear you should immediately inform your doctor

- Tinnitus or ringing in the ears.
- Bilateral or unilateral hearing loss.
- Dizziness.
- Incoordination of movements.
- Unsteadiness of gait.
- Oscillating or bouncing vision.

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

Children and adolescents

According to the data available, toxicities of the kidney and ear nerve remain rare in newborns and children.

Other medicines and Gentamicin

Tell your doctor if you are using, have recently used or might use any other medicines.

Your doctor should take special attention if you are taking the following medicines:

PANPHARMA

22.08.2024

MOCK-UP TYPE

- [ ] box
- [x] leaflet
- [ ] label
- [ ] bag
- [ ] overwrap
- [ ] blisters
- [ ] box label
- [ ] other:

PRODUCT	*Gentamicine*
Country	*UK*
Dimensions	*210 × 250*
ADC code	*PIM-MOCKUP-2023-0015*
Visa	*RTo*

PANTONES

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