



**GENTA® 80 mg, injectable solution**  
**GENTA® 40 mg, injectable solution**  
**GENTA® 20 mg, injectable solution**  
**GENTA® 10 mg, injectable solution**  
**Gentamicin**

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

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

**What is in this leaflet ?**

1. What is GENTA, injectable solution and in which case is it used ?
2. What you need to know before you take GENTA, injectable solution ?
3. How to take GENTA, injectable solution ?
4. Possible side effects
5. How to store GENTA, injectable solution ?
6. Content of the packaging and other information

**1. What is GENTA, injectable solution and in which case is it used ?**

pharmacotherapeutic Class : Other aminoglycosides, ATC code : J01GB03  
 GENTA, injectable solution, is indicated in adults and children:

- As a curative treatment of severe infections caused by identified bacterial species or suspected, microbiologically sensitive gentamicin. Under these conditions, GENTA, injectable solution, may be used:

- o in the following diseases :
- o Urinary infections,
- o Infections during inflammation of the inner lining of the heart
- o Infections of the membranes enveloping the central nervous system
- o Bone and joint infections
- o Listeriosis (whole body infections due to the presence of *Listeria monocytogenes* in the blood)

• As a prophylactic treatment of post-operative infections and during radiological procedures and interventional medicine, according to the recommendations of good use of antibiotics.

**2. What you need to know before you take GENTA, injectable solution ?**

**Never take GENTA**  
 • If you take GENTA, injectable solution :

- If you are allergic to gentamicin or to one of the other components contained in this medicine, listed in section 6.
- In case of liver diseases
- In case of muscle fatigue
- In subcutaneous administration due to lack of efficacy and the occurrence of necrosis at the injection site, with simultaneous administration of another medicine of the same therapeutic class.

**Warning and precautions**

GENTA should not be used by inhalation due to risk of severe allergic reactions, such as bronchospasm. Talk to your doctor or pharmacist first before using GENTA.

Your doctor needs to know if :

- you are pregnant or breastfeeding
  - you have impaired kidney function
  - you suffer from deafness.
- In these cases, you will receive gentamicin only if your doctor considers this treatment as necessary to treat your disease. Your doctor will take special precaution so exactly adjust your dose of gentamicin. Your doctor will be especially careful if you have a disease affecting your nerve and muscle function, such as Parkinson's disease, or if you receive a muscle relaxant during surgery because gentamicin can cause a blocking effect on your nerve and muscle function.

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

To reduce the risk of injury at your kidneys and nerves in your ears, your doctor will carefully monitor the following recommendations:

- Monitoring of hearing, balance and kidney function before, during and after treatment.
- Choosing a dosage adapted to your kidney capacity.
- Monitoring the blood concentration of gentamicin during treatment if your case requires.
- This medication should be avoided if you are taking Polymyxin B or Biotinum toxin.
- Avoid the administration of other substances that can cause damage to the nerves of the ear or kidney, along with gentamicin. If this can not be avoided, close monitoring of your kidney function is necessary.

**Children and adolescents**

Not applicable.

**Other medicines and GENTA, injectable solution**

Tell your doctor or pharmacist if you take, have recently taken or may take any other medicine.

**Medicines that can damage the kidneys and hearing**

There is an increased risk of side effects in patients receiving or about to receive treatment with medicines that can potentially damage the kidneys or hearing, such as : amphotericin B (antifungal agent), polymyxin B or ceftazidime (antibiotics), cisplatin (a medicine to suppress immune system reactions), cisplatin (a medicine used as an anti-cancer treatment), other antibiotics in the aminoglycosides, loop diuretics (used to increase urine output) such as furosemide, tacrolimus (used after organ transplantation).

Medicines that may be affected by Gentamicin

Simultaneous administration of botulinum toxin and gentamicin may increase the effect of botulinum toxin.

The administration of gentamicin with curares (muscle relaxants) may increase their relaxing effect.

**GENTA, injectable solution with food, drinks and alcohol**

Not applicable.

**Pregnancy and breast feeding**

If you are pregnant or breastfeeding, if you think you may be pregnant or planning pregnancy, ask your doctor or pharmacist before taking this medicine.

**Pregnancy**

The use of this medicine is not recommended, unless advised by your doctor, during pregnancy.

If you discover that you are pregnant during treatment, consult your doctor quickly : only he can adapt the treatment to your condition.

In case of exposure during pregnancy, it is recommended to evaluate the hearing function of the newborn.

**Breastfeeding**

Breastfeeding is possible in case of treatment with gentamicin.

**Driving and using machines**

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

**2. How to take GENTA, injectable solution ?**

[GENTA should not be administered by inhalation.

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist in case of doubt.

**Dosage**

Dosage will be adjusted to the severity of the clinical picture, the site, the patient's renal function and identified bacteria.

**INTRAVENOUS AND INTRAMUSCULAR ROUTES**

The administration schedules are identical for the intravenous route and for the intramuscular route.

• For information in the subject with normal-renal function :

- o Adults : 3 to 8 mg/kg/day
- o Infants and Children : 3 to 8 mg/kg/day. Special attention should be paid to the preparation (dilution) and the quantity administered. Any error, however small, can have a major impact on the serum concentrations obtained.
- o Newborns : 3 to 8 mg/kg/day. Dosages should be adjusted according to post-conceptual age, taking into account the effective recommendations. Special attention should be paid to the preparation (dilution) and the quantity administered. Any error, however small, can have a major impact on the serum concentrations obtained.

• For information in the subject of renal insufficiency:

- o First injection : 3 to 8 mg/kg/day
- o If multiple injections: practice reinjections at the same dose as a first injection, unless there is a need for an adjustment of the unit dose based on peak dosage.
- o In case of dialysis, the injections must be done 2 to 4 hours before the dialysis session to reduce the toxicity potential.
- For information in the elderly :

Treatment modalities should be adjusted to kidney function.

• For information in the obese subject:

- o The dose in mg /kg should be calculated based on the corrected weight.
- For information in the liver insufficiency subject:

Gentamicin is contraindicated in severe liver problems. If it's not the case, gentamicin prescription is

possible and no dosage adjustment is necessary.

**Method and route of administration**

Intravenous (30-minute infusion) or intramuscular administration.  
 For the intravenous route, the quantity of gentamicin to be administered is to be diluted in a solution for infusion (Glucose 5% or NaCl 0.9%) at a rate of 50 to 200 ml approximately while respecting a maximum concentration of 10 mg / ml/ml.

**If you have taken more GENTA, injectable solution, than you should**

If you take more GENTA than needed, contact your doctor and stop the treatment. In case of overdose, dialysis may be recommended.

**If you forget to take GENTA, injectable solution**

Not applicable.

**If you stop taking GENTA, injectable solution**

Not applicable.

If you have any further questions about the use of this medicine, ask your doctor, pharmacist or nurse for more information.

**4. Possible side effects**

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

The frequencies are defined by :

- Very common (≥ 1 / 10)
- Common (≥ 1 / 100 to < 1 / 10)
- Uncommon (≥ 1 / 1 000 to < 1 / 100)
- Rare (≥ 1 / 10 000 to < 1 / 1 000)
- Very rare (< 1 / 10 000).

Not known frequency (cannot be estimated on the basis of the available data)

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

• Alteration of renal function

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

• Blood coagulation disorder

• More or less redness of the skin without papules or vesicles

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

- Low blood levels of potassium, calcium and magnesium
- Increased levels of aldosterone in the blood
- Loss of appetite
- Loss of weight
- Illness affecting several peripheral nerves
- Disorder of perception of sensations
- Vomiting, nausea
- Increased liver enzymes and urea in the blood (all reversible)
- Increased salivation
- Inflammation of the oral mucosa
- Red colouring of the skin
- Muscle pain
- Increased body temperature

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

- Superinfection (with gentamicin-resistant germs)
- Very severe inflammation of the colon
- Blood disorders affecting certain blood elements and usually detected by blood tests
- Hypersensitivity reactions (rash, itchy skin)
- Anaphylactic shock
- Decrease in the amount of phosphates in the blood
- Confusion, hallucinations, depression
- Set of brain disorders
- Convulsions
- Neuromuscular Blocking
- Dizziness, vertigo, balance disorders, headache
- Vision disorders
- Loss of hearing
- Affection of the inner ear, tinnitus
- Low blood pressure
- High blood pressure
- Serious allergic reaction of the skin and mucous membranes with vesicles and redness of the skin (erythema multiforme) which can, in very serious cases, affect the internal organs and be life-threatening (Stevens-Johnson syndrome, toxic epidermal necrolysis), skin detachment (toxic epidermal necrolysis, or Lyell's syndrome)
- Hair loss
- Atrophy of the muscles
- Acute renal failure, elevated levels of phosphate in the urine and amino acids (known as Fanconi syndrome, associated with long-term use of high doses)
- Pain after injection sites

**Not known frequency (cannot be estimated on the basis of the available data)**

• Irreversible loss of hearing, deafness

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This also applies to any side effects that are not mentioned in this leaflet. You can also report side effects directly via the national reporting system : National Center of Pharmacovigilance (NCPV). By reporting side effects, you can help provide more information on the safety of the medicine.

**5. How to store GENTA, injectable solution**

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

No special storage conditions

Do not use this medicine after the expiry date which is stated on the box after EXP. The expiry date refers to the last day of this month.

After opening : the product must be used immediately.

Do not dispose of any medicines to wastewater or household waste. Ask your pharmacist to eliminate medicines you no longer use. These measures will help protect the environment.

**6. Content of the packaging and other information**

**What GENTA, injectable solution contains**

	GENTA 80 mg	GENTA 40 mg	GENTA 20 mg	GENTA 10 mg
<b>Active substance</b>	Gentamicin 40 mg/ml in the form of gentamicin sulfate for 2 ml of solution.	Gentamicin 20 mg/ml in the form of gentamicin sulfate for 2 ml of solution.	Gentamicin 10 mg/ml in the form of gentamicin sulfate for 2 ml of solution.	Gentamicin 10 mg/ml in the form of gentamicin sulfate for 1 ml of solution.
<b>Excipients</b>	Methyl parahydroxybenzoate, propyl parahydroxybenzoate, sodium edetate, water for injections.			

**What GENTA injectable solution looks like and content of the outer packaging**

Type I neutral glass ampoules

Genta 80: box of 1, 5 and 50 ampoules of 2 ml.

Genta 40: box of 5 and 50 ampoules of 2 ml.

Genta 20: box of 5 and 50 ampoules of 2 ml.

Genta 10: box of 5 and 50 ampoules of 1 ml.

**Supply and prescription Condition: List I**

**M.A.N. :**

GENTA 80 mg, injectable solution, B/1/2ml : 9233054

GENTA 40 mg, injectable solution, B/5/2ml : 9233051

GENTA 80 mg, injectable solution, B/50/2ml : 9233052H

GENTA 40 mg, injectable solution, B/5/2ml : 9233101

GENTA 40 mg, injectable solution, B/50/2ml : 9233102H

GENTA 20mg, injectable solution, B/5/2ml : 9233091

GENTA 20mg, injectable solution, B/50/2ml : 9233092H

GENTA 10 mg injectable solution, B/5/1 ml : 9233093.

GENTA 10 mg, injectable solution, B/50/1 ml : 9233094H.

**Marketing Authorisation Holder :**

**LES LABORATOIRES MEDIS - S.A.**

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**This is a medicine**

- A medicine is a product but not like any other product.
- A medicine is a product that affects your health, if it's not used properly : it can be health threatening.
- Strictly adhere to the prescription of your Doctor and the use instructions prescribed, follow your pharmacist advice.
- Your doctor and you pharmacist know the medicine, its use and side effect.
- Don't stop the use of the treatment on your own during the prescribed time.
- Don't retake. Don't increase the doses without doctor's advice.

**Keep the medicines out of reach of children**



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