1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GENTA 50 mg/ml solution for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Gentamicin sulphate equivalent to Gentamicin 50 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium citrate	
Methyl parahydroxybenzoate (E218)	0.45 mg
Propyl parahydroxybenzoate (E216)	0.05 mg
Sodium metabisulphite (E223)	1.4 mg
Water for injections	

Clear, almost colourless solution for injection.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

For the treatment of septicaemia and infections of the gastro-intestinal and urogenital tracts and skin caused by organisms sensitive to gentamicin.

3.3 Contraindications

Do not use in animals with impaired renal function.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in pregnant animals.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Do not administer in association with general anaesthetics or muscle relaxant drugs, in order to avoid neuromuscular block (respiratory paralysis).
Do not exceed the stated dose.
Use the veterinary medicinal product with care in young animals.
Use of the veterinary medicinal product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands before and after treatment.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse reactions

Cattle:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1]
Undetermined frequency (cannot be estimated from the available data)	Deafness[2], Vestibular disorder[2] Renal disorder[3]

[1]Transient.
[2] Ototoxicity may occur after prolonged administration.
[3] Renal function disturbance may occur after prolonged administration. In particular, young animals appear to be sensitive to the nephrotoxic signs of gentamicin.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
The use during pregnancy is contra-indicated due to the possible nephro- and ototoxicity in the foetus.

3.8 Interaction with other medicinal products and other forms of interaction

- Quickly acting diuretics administered concurrently with gentamicin increase the likelihood of nephrotoxicity and ototoxicity.
- Gentamicin potentiates the action of general anaesthetics and muscle relaxants resulting in a higher risk of neuromuscular block.
- Halothanes raise the cardiovascular depressing effect of gentamicin.

3.9 Administration routes and dosage

For intramuscular injection. To ensure a correct dosage body weight should be determined as accurately as possible.
Dosage: 2 mg gentamicin/kg body weight, equivalent to 4 ml veterinary medicinal product per 100 kg b.w., twice daily for 3-7 days. Where the dose volume is large, the dose should be divided and administered at separate sites.
Repeated injections should be made at different injection sites.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Relative overdosing with neuromuscular block is possible when gentamicin is administered concurrently with general anaesthetics and/or muscle relaxants.
Antidotes: calcium salts or anticholinesterases (neostigmine) in case of respiratory paralysis.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Due to accumulation of gentamicin in liver, kidneys and injection site, any repeated course of treatment during the withdrawal period must be avoided.

Meat and offal: 214 days.
Milk: 7 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATC vet code: QJ01GB03.

4.2 Pharmacodynamics

This veterinary medicinal product contains gentamicin sulphate, the water soluble salt of the antibiotic gentamicin, that belongs to the aminoglycosides. Gentamicin is a broad spectrum antibiotic that is active against:

a) Gram-negative germs such as *E. coli, Shigella, Salmonella, Proteus, Pseudomonas, Klebsiella* and *Pasteurella*.
b) Some Gram-positive germs such as *Staphylococcus, Streptococcus* and *Corynebacterium.*
c) *Mycoplasma* spp.

The Minimum Inhibitory Concentrations (MIC) *in vitro* are between 0.1 and 10 μg/ml. Gentamicin inhibits the bacterial protein synthesis at the level of the 30S ribosomal subunit and this interferes with the uptake of phenylalanine. At high concentrations the structure of the bacterial cell wall is irreversibly damaged so that there is a lysis of the bacterial cell. Gentamicin has a bacteriostatic activity at low concentrations and has a bactericidal activity at high concentrations.

4.3 Pharmacokinetics

Gentamicin is quickly and completely absorbed from the site of injection.

Gentamicin diffuses well in the extracellular fluids and penetrates well in the different tissues, though to a lesser extent in the cerebrospinal liquid and in the mammary gland. It is excreted unchanged through the kidneys.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

The solution is incompatible with alkalic products (precipitation). Gentamicin should not be mixed with penicillins, cephalosporins, chloramphenicol or sulfonamides in the same syringe.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not store above 25 °C. Protect from light.

5.4 Nature and composition of immediate packaging

Type II amber glass vials with bromobutyl rubber stoppers, sealed with an aluminium cap, containing 50 ml or 100 ml of a sterile colourless to pale yellow aqueous solution.
The vials are individually packed in a cardboard box or packed in a polystyrene box with 12 vials per box.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Kela nv

7. MARKETING AUTHORISATION NUMBER

VPA10981/011/001

8. DATE OF FIRST AUTHORISATION

01/10/2003

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

27/03/2025

10 CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).