1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Genta 50 mg/ml solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substances		
Gentamicin sulphate equivalent to Gentamicin	50	mg
Excipients		
Methyl Parahydroxybenzoate (E218)	0.45	mg
Propyl Parahydroxybenzoate (E216)	0.05	mg
Sodium Metabisulphite (E223)	1.4	mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Clear, almost colourless solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not use in animals with impaired renal function.
Do not use in animals with known hypersensitivity to the active ingredient.
Do not use in pregnant animals.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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 GENTA 50 Injectable with care in young animals.
Use of the 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 Product to Animals

Wash hands before and after treatment.

4.6 Adverse reactions (frequency and seriousness)

- Transient swelling may occur at the injection site.
- Renal function disturbance, ototoxicity (deafness and balance disturbances) may occur after prolonged administration. In particular, young animals appear to be sensitive to the nephrotoxic signs of gentamicin.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

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 GENTA 50 mg/ml 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 sites.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Relative overdosing resulting in 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.

4.11 Withdrawal period(s)

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Phamacotherapeutic group: Antibacterials for systemic use, gentamicin.
ATCvet code: QJ01GB03

5.1 Pharmacodynamic properties

GENTA 50 Injectable 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.

5.2 Pharmacokinetic particulars

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 fluid and in the mammary gland. It is excreted unchanged through the kidneys.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Citrate
Methyl Parahydroxybenzoate (E218)
Propyl Parahydroxybenzoate (E216)
Sodium Metabisulphite (E223)
Water for Injections

6.2 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.

6.3 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

6.4 Special precautions for storage

Do not store above 25°C. Protect from light

6.5 Nature and composition of immediate packaging

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

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Kela n.v.
St. Lenaartsweg, 48
2320 Hoogstraten
Belgium

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10981/011/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2008

10 DATE OF REVISION OF THE TEXT

November 2017