ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GentaDug

85 mg/ml, solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml solution for injection contains:

Active substance:
Gentamicin sulphate 85 mg
(equivalent to Gentamicin 50 mg)

3. PACKAGE SIZE

1 x 100 ml
6 x 100 ml
12 x 100 ml

4. TARGET SPECIES

Horses (non-food producing horses), cattle, pigs, dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For slow intravenous use in horses.
For intramuscular or slow intravenous injection in cattle and pigs.
For intramuscular, subcutaneous or slow intravenous injection in dogs and cats.

7. WITHDRAWAL PERIODS

Withdrawal period:

Not authorised for use in horses producing meat or milk for human consumption.

Following intramuscular or intravenous injection:

Cattle:	Meat and offal:	214 days
	Milk:	7 days
Calves:	Meat and offal:	192 days
Pigs, piglets, weaners:	Meat and offal:	146 days

Due to accumulation of gentamicin in liver, kidneys and injection site, treatment should not be repeated during the withdrawal period.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 14 days.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Bela-Pharm GmbH & Co.KG

14. MARKETING AUTHORISATION NUMBERS

Vm 41816/3000

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{100 ml vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GentaDug
85 mg/ml, solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml solution for injection contains:

Active substance:

Gentamicin sulphate	85 mg
(equivalent to Gentamicin	50 mg)

3. TARGET SPECIES

Horses (non-food producing horses), cattle, pigs, dogs and cats.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:

Not authorised for use in horses producing meat or milk for human consumption.

Cattle:	Meat and offal:	214 days
	Milk:	7 days
Calves:	Meat and offal:	192 days
Pigs, piglets, weaners:	Meat and offal:	146 days

Due to accumulation of gentamicin in liver, kidneys and injection site, treatment should not be repeated during the withdrawal period.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within: 14 days
Once opened used by:…

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Bela-Pharm GmbH & Co.KG

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

GentaDug
85 mg/ml, solution for injection for horses, cattle, pigs, dogs and cats.

2. Composition

1 ml solution for injection contains:

Active substance:
Gentamicin sulphate 85 mg
(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
Methyl parahydroxybenzoate	0.9 mg
Propyl parahydroxybenzoate	0.1 mg

A clear, colourless to slight yellow solution.

3. Target species

Horses (non-food producing horses), cattle, pigs, dogs and cats.

4. Indications for use

Treatment of the following infections:

Horses: for the treatment of infections of the lower respiratory tract in horses caused by aerobic Gram-negative bacteria.
Cattle: infections of the genital tract.
Calves: infections of the respiratory tract, infections of the gastro-intestinal tract, septicaemia, infections of the joints, infections of the auditory meatus.
Pigs: infections of the respiratory tract, metritis, mastitis and agalactia (MMA) complex.
Piglets, weaners: infections of the respiratory tract, enzootic pneumonia, infections caused by *E. coli*.
Dogs, cats: infections of the respiratory tract, infections of the gastro-intestinal tract, infections of the kidneys, the urinary and the genital tract, septicaemia, infections of the auditory meatus.

5. Contraindications

Do not use in animals with impaired renal function.
Do not use in dehydrated animals due to the risk of acute renal failure.
Do not use in animals with disturbances of the vestibular or auditory systems.
Do not use in cases of known hypersensitivity to the active substance or to any of the excipients.
Do not inject intravenously if used concomitantly with muscle relaxants.
Do not use concomitantly with bacteriostatic antibiotics.
Do not administer concurrently with diuretics and potentially nephrotoxic medicinal products.
Do not exceed the proposed dosing regimen.

6. Special warnings

Special warnings:
Within the group of aminoglycosides, complete cross-resistance is often observed.

Special precautions for safe use in the target species:
As gentamicin has a narrow therapeutic margin, to ensure a correct dosage, body weight should be determined as accurately as possible.

Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.
Use of the product should be in accordance with official, national and regional antimicrobial policies.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for the first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Because of the risk of occurrence of neuromuscular blockade, veterinary medicinal product must be injected slowly when administered intravenously.

In dehydrated animals, fluid balance should be restored before treatment is initiated.

Horses:
Gentamicin is well known to induce nephrotoxicity even at therapeutic doses. There are also isolated reports of ototoxicity with gentamicin. No margin of safety has been established under the approved dosing regimen. As such, gentamicin has a narrow margin of safety.

The product should therefore only be used based on the benefit-risk assessment by the responsible veterinary surgeon for each individual horse, taking into account alternative available treatment.

In order to reduce the nephrotoxic risk, adequate hydration of animals under treatment should be ensured, and fluid therapy should be instituted, if required.

Close monitoring of horses being treated with gentamicin is strongly advised. This monitoring includes assessing relevant kidney parameters in blood (e.g. creatinine and urea) and urinalysis (e.g. gamma glutamyl transferase/creatinine ratio). Therapeutic blood monitoring of gentamicin concentration is also recommended because of known individual animal variations in peak and trough gentamicin plasma concentrations. Where blood monitoring is available, target peak plasma gentamicin concentrations should be approximately 16–20 µg/ml.

Particular caution should be taken when administering gentamicin with other potential nephrotoxic medicinal products (containing e.g. NSAIDs, furosemide, and other aminoglycosides).

Safety of gentamicin has not been established in foals and there is a lack of knowledge of the extra effects of gentamicin on foal kidneys, especially neonates. Current knowledge suggests that foals, especially neonates, are at a higher risk of gentamicin-induced nephrotoxicity compared to adults. Differences between neonatal foal kidneys and adults include a slower clearance of gentamicin in foals. As such, no margin of safety has been established in neonatal foals. It is therefore not recommended to use the product in foals.

Whenever possible, use of the product should be based on susceptibility testing of the bacteria isolated from the animal. Gentamicin is a narrow-spectrum Gram-negative bactericidal antimicrobial, without effects on anaerobe bacteria and mycoplasmas. Gentamicin does not penetrate intracellularly, or into abscesses. Gentamicin is de-activated in the presence of inflammatory debris, low oxygen environments and low pH.

The dosing regimen must not be exceeded. Use of the product deviating from the instructions given in the SPC increases the risk of nephrotoxicity, and may increase the prevalence of bacteria resistant to gentamicin.

Extra caution is advised if using gentamicin in old horses, or with fever, endotoxemia, sepsis and dehydration.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to gentamicin, sodium metabisulfite or methyl- or propyl parahydroxybenzoate should avoid contact with the veterinary medicinal product.

Pregnancy and lactation:
The safety in pregnant horses has not been established. However, studies in laboratory animals have shown evidence of foetal nephrotoxicity. Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
When treating simultaneously with other pharmaceuticals, they should always be administered separately to avoid possible inactivation.
Do not use concomitantly with other oto- or nephrotoxic drugs.
Combined therapy with suitable antibiotics (e.g. ß-lactam antibiotics) may lead to a synergistic effect. Synergistic effects with acylaminopenicillins on *Pseudomonas aeruginosa* and with cephalosporins on *Klebsiella pneumoniae* have been described.

Please note that cross allergy to other aminoglycoside antibiotics may occur.

Overdose:
Overdosage as well as a rapid intravenous injection may cause neuromuscular blockade possibly leading to convulsions, respiratory distress and circulatory depression. In case of neuromuscular blockade, associated with convulsions, respiratory distress and collapse, the drug must be withdrawn immediately. Calcium or neostigmine should be injected, if necessary.
In case of allergic or anaphylactic reactions, treatment should be discontinued immediately and therapy with epinephrine, antihistamines, and /or glucocorticoids should be initiated.
Due to the oto- and nephrotoxic potential of gentamicin, corresponding symptoms may occur following overdosage. Treatment should be discontinued immediately.

Special restrictions for use and special conditions for use:
Not applicable.

Major incompatibilities:
Incompatibilities exist with amphotericin, heparin, sulfadiazine, various penicillins and cephalosporins, chloramphenicol hydrogensuccinate sodium, oxacillin, vitamin B-complex.
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Horses (non-food producing horses), cattle, pigs, dogs and cats:

Undetermined frequency (cannot be estimated from the available data):	Vestibular disorder[1] Internal ear disorder[1] Renal disorders[1] Proteinuria[2]

[1] May occur when administered for a treatment period exceeding the recommendations.

[2] Renal disorders may result in proteinuria associated with elevated blood urea nitrogen.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

Horses:

For slow intravenous use.
Single dose of 11.2 mg gentamicin sulphate (= 6.6 mg gentamicin) per kg bodyweight, corresponding to 6.6 ml solution for injection per 50 kg bodyweight given intravenously once daily for 3 - 5 consecutive days.

To ensure a correct dosage, bodyweight should be determined as accurately as possible. The dosing regimen should not be exceeded. The use of gentamicin in foals and neonates is not recommended.

Cattle, pigs:

For intramuscular or slow intravenous injection.
5.9 mg gentamicin sulphate (= 3.5 mg gentamicin) per kg bodyweight corresponding to 3.5 ml of the veterinary medicinal product per 50 kg bodyweight given twice daily at intervals of 12 hours for 3 to 5 days.

Calves, weaners, piglets in the first months of life:

Initial treatment:
5.9 mg gentamicin sulphate (= 3.5 mg gentamicin) per kg bodyweight corresponding to 0.7 ml of the veterinary medicinal product per 10 kg body weight
Second and subsequent injections:
2.9 mg gentamicin sulphate (= 1.75 mg gentamicin) per kg bodyweight corresponding to 0.3 ml of the veterinary medicinal product per 10 kg bodyweight given twice daily at intervals of 12 hours for 3 to 5 days.

For intramuscular, subcutaneous or slow intravenous injection in dogs and cats.

Dogs older than 2 weeks:

6.5 mg gentamicin sulphate (= 3.85 mg gentamicin) per kg bodyweight corresponding to 0.8 ml of the veterinary medicinal product per 10 kg bodyweight given twice daily at intervals of 12 hours on the first day, thereafter once daily at intervals of 24 hours for 3 to 10 days.

Dogs younger than 2 weeks:

Initial treatment:
6.5 mg gentamicin sulphate (= 3.85 mg gentamicin) per kg bodyweight corresponding to 0.23 ml of the veterinary medicinal product per 3 kg bodyweight
Second and subsequent injections:
3.25 mg gentamicin sulphate (= 1.925 mg gentamicin) per kg bodyweight corresponding to 0.12 ml of the veterinary medicinal product per 3 kg bodyweight given twice daily at intervals of 12 hours on the first day, thereafter once daily at intervals of 24 hours for 3 to 10 days.

Cats older than 2 weeks:

4.32 mg gentamicin sulphate (= 2.56 mg gentamicin) per kg bodyweight corresponding to 0.25 ml of the veterinary medicinal product per 5 kg bodyweight given twice daily at intervals of 12 hours for 3 to 10 days.

Cats younger than 2 weeks:

Initial treatment:
4.32 mg gentamicin sulphate (= 2.56 mg gentamicin) per kg bodyweight corresponding to 0.13 ml of the veterinary medicinal product per 2.5 kg bodyweight
Second and further injections:
2.16 mg gentamicin sulphate (= 1.28 mg gentamicin) per kg bodyweight corresponding to 0.06 ml of the veterinary medicinal product per 2.5 kg bodyweight given twice daily at intervals of 12 hours for 3 to 10 days.

9. Advice on correct administration

To ensure a correct dosage, bodyweight should be determined as accurately as possible. The dosing regimen should not be exceeded. The use of gentamicin in foals and neonates is not recommended.
In pigs do not administer more than 1 ml per injection site.
Repeated injections should be made at different injection sites.
If no significant clinical improvement is noted within 3 days of treatment, the initial diagnosis should be reassessed and the therapy should be changed, if necessary.
In case an extended treatment is required, kidney function should be monitored.

The closure should not be pierced more than 50 times.

10. Withdrawal periods

Not authorised for use in horses producing meat or milk for human consumption.

Following intramuscular or intravenous injection:

Cattle:	Meat and offal:	214 days
	Milk:	7 days
Calves:	Meat and offal:	192 days
Pigs, piglets, weaners:	Meat and offal:	146 days

Due to accumulation of gentamicin in liver, kidneys and injection site, treatment should not be repeated during the withdrawal period.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.
The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 14 days

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Cardboard box containing 1x100 ml, 6x100 ml or 12x100 ml glass vial.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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

16. Contact details

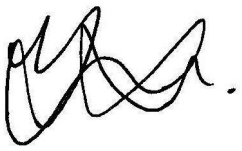
Marketing authorisation holder and manufacturer responsible for batch release:

Bela-Pharm GmbH & Co.KG
Lohner Str. 19
49377 Vechta
Germany

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information



Approved: 28 July 2023