IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

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

PRODUCT SUMMARY

EU Procedure number	IE/V/0772/001/DC
Name, strength and pharmaceutical form	GentaDug 85 mg/ml solution for injection
Active substance(s)	Gentamicin sulphate
Applicant	Bela-Pharm GmbH & Co. KG Lohner Straße 19 Vechta, Lower Saxony 49377, Germany *LOC-100002906*
Legal basis of application	A generic application in accordance with Article 18 of Regulation (EU) 2019/6.
Date of completion of procedure	22/02/2023
Target species	Horses (non-food producing horses), cattle, pigs, dogs and cats
Indication 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.
ATC vet code	QJ01GB03
Concerned Member States	UK(NI)

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the Health Products Regulatory Authority (HPRA) at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in relevant articles of Regulation (EU) 2019/6. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

I. SCIENTIFIC OVERVIEW

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.
It has been shown that the product can be safely used in the target species; the reactions observed are indicated in the SPC.
The product is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.
The efficacy of the product was demonstrated according to the claims made in the SPC.
The overall benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Qualitative and Quantitative Particulars

The product contains 85 mg/ml of the active substance gentamicin sulfate and the excipients methyl parahydroxybenzoate, propyl parahydroxybenzoate, sodium metabisulfite and water for injections.
The container/closure system is 100 ml clear type II glass vials with bromobutyl rubber stoppers and aluminium caps.
The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.
Process validation data for the manufacturing process has been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is gentamicin sulfate, an established substance described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.
The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification has been provided.

Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies
Compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

D. Control on Intermediate Products

Not applicable.

E. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.
Satisfactory validation data for the analytical methods has been provided.
Batch analytical data from the proposed production site has been provided demonstrating compliance with the specification.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

This application has been submitted in accordance with Article 18 of Regulation (EU) 2019/6 (generic veterinary medicinal product). As bioequivalence with the reference product has been accepted, the results of safety tests are not required.
The applicant has cited a suitable reference product, 'Vetogent Inj. 85 mg/ml' which has been authorised for in excess of ten years and can be accepted as a valid reference product in this generic application. The applicant claimed a waiver from the requirement to provide *in vivo* bioequivalence data based on compliance with conditions set out in section 7.1 of the CVMP Guideline on the conduct of bioequivalence studies for veterinary medicinal products. This waiver was accepted.
The safety aspects of this product are considered to be the same as the reference product.
Warnings and precautions as listed on the product literature are similar to those of the reference product and are adequate to ensure safety of the product to users, consumers and the environment.

III. SAFETY ASSESSMENT

III.A Safety Testing

Pharmacological Studies

No pharmacodynamic or pharmacokinetic data were presented. Given the legal basis of this application and accepted bioequivalence with the reference product, omission of these data was accepted.

Toxicological Studies

No toxicological study data were presented. Given the legal basis of this application and accepted bioequivalence with the reference product, omission of these data was accepted.

User Safety

The following user safety warning is included in the SPC, and is similar to that approved for the reference product.

"People with known hypersensitivity to gentamicin, sodium metabisulfite or methyl- or propyl parahydroxybenzoate should avoid contact with the veterinary medicinal product."

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

Phase I

The environmental risk assessment can stop in Phase I for the target species horses (non-food producing horses) dogs and cats, and no Phase II assessment is required. The Phase I assessment also returned PEC_{soil} calculations of less than 100 µg/kg for use in cattle, calves, and pigs, and reference to Article 18(7) of Regulation (EU) 2019/6 was made in respect of use of the product in fattening pigs.

Conclusion

Based on the data provided, the ERA can stop at Phase I. The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

III.B Residues Documentation

Residue Studies

No residue depletion studies were conducted because no difference in residue depletion between the candidate and reference products was anticipated. Based on acceptance of this conclusion, the withdrawal period of the reference product was extrapolated to the candidate product.

MRLs

Gentamicin is listed in Table I of the Annex to Commission Regulation (EU) No 37/2010 as follows:

	Cattle	**Pigs**
Muscle	50 µg/kg	50 µg/kg
Liver	200 µg/kg	200 µg/kg
Kidney	750 µg/kg	750 µg/kg
Fat	50 µg/kg	50 µg/kg
Milk	100 µg/kg	100 µg/kg

Withdrawal Periods

Based on the data provided, the following withdrawal periods are justified:

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

IV. CLINICAL ASSESSMENT

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

The product literature accurately reflects the type and incidence of adverse effects which might be expected.

IV.B Clinical Studies

As this is a generic application according to Article 18 of Regulation (EU) 2019/6, and bioequivalence with a reference product has been accepted, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the benefit/risk profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

VI. POST-AUTHORISATION ASSESSMENTS

Not applicable.