IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Lincovex 100 mg/ml solution for injection for pigs, cats and dogs

PRODUCT SUMMARY

EU Procedure number	IE/V/0787/001/DC
Name, strength and pharmaceutical form	LINCOVEX 100 mg/ml solution for injection for pigs, cats and dogs
Active substance(s)	Lincomycin (as lincomycin hydrochloride monohydrate)
Applicant	S.P. Veterinaria, S.A. Ctra. Reus - Vinyols Km 4, 1 Riudoms 43330 Spain
Legal basis of application	Generic application in accordance with Article 18 of Regulation (EC) 2019/6 as amended.
Date of completion of procedure	20/12/2023
Target species	Dogs, cats and pigs
Indication for use	Dogs and cats: for the treatment of infections caused by Gram-positive organisms, particularly streptococci and some anaerobic bacteria. Pigs: for the treatment of infections caused by Gram-positive bacteria, some anaerobic bacteria and mycoplasma.
ATC vet code	QJ01FF02
Concerned Member States	BG, ES, IT, PL, PT, RO
Withdrawn CMS during decentralised procedure	FR. The company decided to withdraw the application. At the time of withdrawal, the MS considered that the data provided did not allow it to conclude on a positive benefit-risk balance as potential serious risk to public health was raised.

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), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

I. SCIENTIFIC OVERVIEW

The veterinary medicinal product (VMP) is produced and controlled using validated methods and tests, which ensure the consistency of the VMP released on the market.
It has been shown that the VMP can be safely used in the target species; the reactions observed are indicated in the SPC.
The VMP 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 VMP was demonstrated according to the claims made in the SPC.
The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Qualitative and Quantitative Particulars

The product contains 100 mg/ml of the active substance lincomycin (as lincomycin hydrochloride monohydrate), and the excipients benzyl alcohol and water for injections. 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 lincomycin (as lincomycin hydrochloride monohydrate), 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
There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

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.

F. Stability
Stability data on the active substance has been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.
Stability data on the finished product has been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

G. Other Information
Not applicable.

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).
The reference product is 'Lincocin Sterile Solution'. A waiver from the requirement to provide *in vivo* bioequivalence data was accepted. As bioequivalence with a suitable reference product has been accepted, the results of safety tests are not required. 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.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 formulations of the product and reference product are the same in terms of active substance and excipients. The candidate product is intended to be administered by the same routes of administration at the same dosage and for the same indications for use in the same species as the reference product.
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product, as follows:
This veterinary medicinal product contains lincomycin and benzyl alcohol, which may cause allergic reactions in some individuals. People with known hypersensitivity to lincomycin or any other lincosamide, or to benzyl alcohol should avoid contact with the veterinary medicinal product.
Avoid contact with the product. In case of accidental eye or skin contact, wash off the affected area thoroughly with water. Immediately after use, wash hands with soap and water.
Do not eat, drink or smoke when handling the product.
Take care when administering the product to avoid accidental self-injection. In case of accidental self-injection seek medical attention immediately and show the package leaflet or the label to the physician.
If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing, are more serious symptoms and require urgent medical attention.

Environmental Risk Assessment
An environmental risk assessment (ERA) has not been provided, instead the applicant has cited the approach detailed in the Reflection paper on the interpretation of Article 18(7) of Regulation (EU) 2019/6 (EMA/CVMP/ERA/622045/2020) as a means to justify why an ERA should not be required. It was accepted that an ERA according to VICH GL38 has been performed by a competent authority for a sufficiently similar product and that the applicant should not be required to provide an ERA under Article 18(7) of Regulation (EU) 2019/6.

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.

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

Pharmacologically active substance	Marker residue	Animal Species	MRL	Target tissues	Other provision
Lincomycin	Lincomycin	All food-producing species	100 µg/kg 50 µg/kg 500 µg/kg 1500 µg/kg 150 µg/kg 50 µg/kg	Muscle Fat Liver Kidney Milk Eggs	For fin fish the muscle MRL relates to 'muscle and skin in natural proportions'. MRLs for fat, liver and kidney do not apply to fin fish. For porcine and poultry species the fat MRL relates to 'skin and fat in natural proportions'

Withdrawal Periods
Based on the data provided, the following withdrawal periods are justified:
Pigs:
Meat and offal: 3 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.

Resistance

Adequate warnings and precautions appear on the product literature.

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 VMP is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the quality and safety of the VMP for humans and the environment is acceptable.

VI. POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the VMP. The current SPC is available in the Union Product Database (UPD).

This section contains information on significant changes, which have been made after the original procedure, which are important for the quality, safety or efficacy of the VMP.

Changes:

None.