IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Lyncoo 400 mg/g powder for use in drinking water for pigs and chickens

PRODUCT SUMMARY

EU Procedure number	IE/V/0606/001/DC
Name, strength and pharmaceutical form	Lyncoo 400 mg/g powder for use in drinking water for pigs and chickens
Active substance(s)	Lincomycin
Applicant	Endectovet EOOD Mihail Takev Street 108 Floor 2 Apartment 3, 4550 Peshtera, Bulgaria
Legal basis of application	Generic application in accordance with Article 18 of Regulation (EC) 2019/6 as amended.
Date of completion of procedure	
Target species	Pigs and chickens
Indication for use	Pigs Treatment and metaphylaxis of enzootic pneumonia caused by *Mycoplasma hyopneumoniae*. The presence of the disease in the group must be established before the veterinary medicinal product is used. Chickens Treatment and metaphylaxis of necrotic enteritis caused by *Clostridium perfringens*. The presence of the disease in the flock must be established before the veterinary medicinal product is used.
ATC vet code	QJ01FF02
Concerned Member States	BE, BG, CY, CZ, DE, DK, EE, EL, ES, FR, HR, HU, LT, LV, LU, MT, NL, PL, PT, RO, SI, SK, 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), 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

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A. Qualitative and Quantitative Particulars

The product contains the active substance lincomycin (as 453.6 mg/g lincomycin hydrochloirde) and the excipient lactose monohydrate. The container/closure system is standard for this dosage form and is described in the SPC. 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 lincomycin (as lincomycin hydrochloride) is an established active substance 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 theTransmission 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 IntermediateProducts
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 applicant has cited a suitable reference product, 'Lincocin Soluble Powder, 400 mg/g powder for use in drinking water' which has been authorised for in excess of ten years and can be accepted as a valid reference product in this generic application. The candidate product is of the same pharmaceutical form (powder for use in drinking water), is intended to be used for the same indications, in the same target species, via the same routes of administration and at the same posology as the reference product. A biowaiver for soluble pharmaceutical forms for in drinking water use based on the Guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/2000-Rev.4) section 7.1c and Appendix 1, section VI.2 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.

III.A Safety Testing
Pharmacological Studies
No pharmacodynamic or pharmacokinetic data have been presented. Given the legal basis of the application (generic VMP) and as bioequivalence with a suitable reference product can be accepted, the omission of these data can also be accepted.

Toxicological Studies

No toxicology data have been presented. As bioequivalence with the reference product can be accepted, and given the legal basis of the application, the omission of toxicological (including reproductive and developmental toxicity), genotoxicity and carcinogenicity data can be accepted as the toxicity profile of the candidate formulation is not expected to differ from that of the reference product.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline. The assessment identified a potential risk following a combined dermal and oral exposure and a potential risk for those with hypersensitivity to lincomycin or the excipient lactose monohydrate. The proposed warnings and safety measures are generally consistent with those detailed in Commission Implementing Decision (2017)6867 of 05 Oct 2017 following the Article 34 referral for Lincocin and its associated names and thus are considered acceptable. The proposed SPC contains the additional information 'In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.' Given the risk identified in the assessment, the inclusion of this additional information was supported.

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

Environmental Risk Assessment

The applicant has not provided a Phase II environmental risk assessment (ERA), instead, reference to the 'Reflection paper on the interpretation of Article 18(7) of Regulation (EU) 2019/6' (EMA/CVMP/ERA/622045/2020) has been made. As noted in the reflection paper, an ERA is no longer routinely required in support of a generic application, subject to a number of criteria being satisfied.

As there are similar VMPs authorised in the EU/EEA after 1 October 2005 it is considered that an ERA according to VICH GL38 and/or any other relevant guidelines in effect at that time has been performed by a competent authority, that the ERA data package provided has been found to be satisfactory and that appropriate risk mitigation measures are in place. Suitable advice was included in the SPC for this product.

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 listed 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: 1 day.

Chickens:

Meat and offal: 5 days.

Not for use in birds producing or intended to produce eggs for human consumption.

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.