



**Veterinary
Medicines
Directorate**

**United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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NATIONAL PROCEDURE

**PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY
MEDICINAL PRODUCT**

Lyncoo 400 mg/g Powder for Use in Drinking Water for Pigs and Chickens

Date Created: December 2025

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Lyncoo 400 mg/g Powder for Use in Drinking Water for Pigs and Chickens
Applicant	Endectovet EOOD 108 Mihail Takev Street Peshetera 4550 Bulgaria
Active substance	Lincomycin
ATC Vetcode	QJ01FF02
Target species	Chicken Pig
Indications for use	Pigs: Treatment and metaphylaxis of enzootic pneumonia caused by <i>Mycoplasma hyopneumoniae</i> . 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 <i>Clostridium perfringens</i> . The presence of the disease in the flock must be established before the veterinary medicinal product is used.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

www.gov.uk/check-animal-medicine-licensed

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 8 of Veterinary Medicine Regulations (VMRs) 2013 (Schedule 1, Para 10) as amended.
Date of conclusion of the procedure	11/11/2025

I. SCIENTIFIC OVERVIEW

The product was submitted for a generic application for authorisation in Great Britain (GB), in accordance with Article 8 of Veterinary Medicine Regulations (VMRs) 2013 (Schedule 1, Para 10) as amended. The reference product is Lincocin Soluble Powder, 400 mg/g powder for use in drinking water, marketed by Zoetis UK Limited, and authorised since January 1993 in the UK.

The applicant claimed exemption from the requirement for bioequivalence studies in accordance with exemption 7.1 c) of the Guideline on the Conduct of Bioequivalence Studies for Veterinary Medicinal Products (EMA/CVMP/016/2000-Rev.4) which was accepted.

Lyncoo 400 mg/g Powder for Use in Drinking Water for Pigs and Chickens contains 400 mg/g of lincomycin (as 453.6 mg of lincomycin hydrochloride monohydrate). The product is indicated for the treatment and metaphylaxis of enzootic pneumonia caused by *Mycoplasma hyopneumoniae* in pigs and the treatment and metaphylaxis of necrotic enteritis caused by *Clostridium perfringens* in chickens.

The dosage for pigs is 10 mg lincomycin per kg b.w. (bodyweight), for 21 consecutive days. The dosage for chickens is 5 mg lincomycin per kg b.w. for 7 consecutive days. The product should be administered via water at an appropriate concentration, depending on the animal's bodyweight.

The distribution category in GB is POM-V, the same as the reference product.

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, any reactions observed are indicated in the SPC¹. 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

¹ SPC – Summary of Product Characteristics.

efficacy² 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. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains lincomycin and the excipient lactose monohydrate.

The container/closure system consists of either a 3-layer foil 150 g heat-sealed sachet made of low-density polyethylene/aluminium/polyester, a 4-layer foil 1 kg heat-sealed bag made of low-density polyethylene/polyamide/aluminium/polyester or a 3-layer foil 5 kg heat-sealed bag made of low-density polyethylene/aluminium/polyamide. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the absence of preservative are justified.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant regulatory guidelines.

II.B. Description of the Manufacturing Method

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.

Process validation data on the product have been presented in accordance with the relevant regulatory guidelines.

II.C. Control of Starting Materials

The active substance is lincomycin, an established active substance described in the European Pharmacopoeia, provided with valid Certificates of Suitability (CEPs). 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 have been provided.

The only excipient, lactose monohydrate, complies with the pharmacopeial monograph.

² Efficacy – The production of a desired or intended result.

The container/closure systems for the active substance are detailed in the CEPs. Compliance of the finished product packaging with the relevant regulatory guidelines was provided, together with details of the sachets and bags.

II.C.4. Substances of Biological Origin

Scientific data and/or certificates of suitability issued by the EDQM have been provided and 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.

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

Not applicable.

II.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 have been provided. Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification. Control tests on the finished product are those appropriate for the pharmaceutical form.

II.F. Stability

Stability data on the active substance have been provided in accordance with applicable regulatory guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable regulatory guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

G. Other Information

The shelf life of the product as packaged for sale is 2 years. The shelf life after first opening the immediate packaging is 7 days for the 150 g sachet and 21 days for the 1 kg and 5 kg bags. The shelf life after dissolution in drinking water according to directions is 24 hours.

The product does not require any special storage conditions.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACOTOXICOLOGICAL)

Due to the generic basis of the application, no new pharmacological or toxicological data were required.

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 / the environment / consumers. The statement 'In case of accidental ingestion, seek medical advice' was also included in the SPC as an additional user warning.

III.A Safety Documentation

Pharmacological Studies

Bibliographical data has been provided to illustrate the pharmacodynamics and pharmacokinetics of the active ingredient. The applicant requested a bio waiver in line with the paragraph 7.1.c of the Bioequivalence Guideline (EMA/CVMP/016/2000-Rev.4), on the basis that the product is an aqueous oral solution at the time of administration, and it contains the active substance at the same concentration as the reference product, which is also presented as an aqueous oral solution at the time of administration. This was supported by a dissolution study, which was performed at the highest concentration of lincomycin, calculated to be 404 mg/l lincomycin in medicated drinking water. Bioequivalence to the reference product was accepted.

Lincomycin is active against some gram-negative bacteria (*Clostridium perfringens*) and mycoplasmas (*Mycoplasma hyopneumoniae*). Lincomycin may be either bactericidal or bacteriostatic.

In pigs, lincomycin is rapidly absorbed following oral administration. A single oral administration of lincomycin hydrochloride, at dose levels of approximately 22, 55 and 100 mg/kg body weight in pigs, resulted in dose related lincomycin serum levels, detected for 24-36 hours after administration. Peak serum levels were observed at 4 hours after dosing. Similar results were observed following single oral doses of 4.4 and 11.0 mg/kg body weight in pigs. Levels were detectable for 12 to 16 hours, with peak concentrations occurring at 4 hours. A single oral dose of 10 mg/kg body weight was administered to pigs to determine the bioavailability. The oral absorption of lincomycin was found to be 53% ± 19%. Repeated dosing of pigs with daily oral doses of 22 mg lincomycin/kg body weight for 3 days indicated no accumulation of lincomycin in the species, with no detectable serum levels of antibiotic after 24 hours post administration.

Crossing the intestinal barrier, lincomycin is widely distributed to all tissues, especially the lungs and joint cavities. The elimination half-life is greater than 3 hours. Approximately 50% is metabolised in the liver and it is eliminated unchanged or in the form of various metabolites in bile and urine. High concentrations of the active form are observed in the intestine.

Chickens were administered lincomycin hydrochloride in the drinking water at a level of approximately 34 mg/litre (5.1-6.6 mg/kg body weight) for seven days. Metabolites comprised more than 75% of total residues in the liver. Unmetabolised lincomycin declined at a slightly faster half-life (5.8 hours) than total residue. Lincomycin and one unknown metabolite comprised >50% of the muscle residue at zero hours. The excreta contained mostly unmetabolised lincomycin (60-85%) during treatment.

Toxicological Studies

The applicant provided bibliographical data which shows that the lowest reported LD₅₀ (median lethal dose) by acute oral administration was >5000 mg/kg b.w. in mice. However, following oral administration to rabbits, lincomycin has been found to be toxic by all routes of administration and no LD₅₀ values have been presented.

In repeated dose studies, the lowest oral No Observed Adverse Event Level (NOAEL) for lincomycin was 100 mg/kg b.w./day, established from a 90-day study in mice.

No relevant effects were observed in studies on fertility or foetal development (except foetal resorption at high doses) and no genotoxic or carcinogenic effects were observed.

The lowest NOAEL, via oral administration, for developmental toxicity studies was 30 mg/kg b.w./day for foetotoxicity in rats. In this study, following oral administration of lincomycin from days 6 to 15 of gestation in rats, foetal resorption was observed (8%) and a corresponding decrease in the number of live foetuses was observed following a dose of 100 mg/kg b.w.

User Safety

A user risk assessment was provided in compliance with the relevant guideline which shows that the risk posed to the user by the product is not expected to differ to that posed by the reference product.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product. Therefore, the following applicant's user recommendations are appropriate:

- This veterinary medicinal product contains lincomycin and lactose monohydrate, either of which can cause allergic reactions in some people. People with known hyper-sensitivity to lincomycin or any other lincosamide, or to lactose monohydrate, should avoid contact with the veterinary medicinal product.
- Care should be taken not to raise and inhale any dust.
- Contact with skin and eyes should be avoided.
- Personal protective equipment consisting of approved dust masks (either a disposable half mask respirator conforming to European Standard EN149 or a non-disposable respirator conforming to European Standard

EN140 with a filter EN143), gloves and safety glasses should be worn when handling and mixing the veterinary medicinal product. If respiratory symptoms develop following exposure, seek medical advice and show this warning to the physician.

- In case of accidental exposure to the skin, eyes or mucous membranes, wash the affected area thoroughly with plenty of water.
- If symptoms such as skin rash or persistent eye irritation appear after exposure, seek medical advice immediately and show the package leaflet or label to the physician.
- Wash hands and any exposed skin with soap and water immediately after use.
- Do not eat, drink or smoke while handling the veterinary medicinal product. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Environmental Safety

Based on Annex 3 of the 'Reflection paper on the interpretation of Article 18(7) of Regulation (EU) 2019/6', no ERA was requested for the product because there are similar veterinary medicinal products authorised in EU/EEA after 01 October 2005. It was determined that the use of this product will not pose a risk to the environment when used as recommended.

III.B Residues documentation

Maximum Residue Limits (MRLs)

Lincomycin is included in the GB MRL list of allowed substances for use in food-producing animals with numerical MRLs established for all food-producing species. The marker substance is lincomycin.

The excipient lactose monohydrate does not require MRL evaluation as it is covered under normal foodstuff as a carbohydrate that is naturally occurring.

Due to the legal basis of the application and as bioequivalence with the reference product was accepted no residue depletion studies were required.

MRLs for lincomycin are listed below:

	All food producing species
Muscle	100 µg/kg
Liver	500 µg/kg
Kidney	1 500 µg/kg
Fat / skin	50 µg/kg
Milk	150 µg/kg
Eggs	50 µg/kg

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 DOCUMENTATION

Due to the legal category of the application, and as bioequivalence with the reference product was accepted, clinical studies were not required. The efficacy claims, dosing regimens, and pharmacology for the product are equivalent to those of the reference product.

Resistance

The applicant submitted a literature review for the active substance, providing recent data as to the current state of lincomycin resistance.

Multiple referenced papers cite the difficulty in *in vitro* growth of *Mycoplasma hyopneumoniae* and lack of break points determined for lincomycin resistance in both *Mycoplasma hyopneumoniae* and *Clostridium perfringens*, making establishing accurate resistance levels to lincomycin in Europe difficult.

The literature review also presented evidence of potential cross resistance across macrolides, lincosamides and streptogramin group B antibiotics. Given the product includes the same active substance at the same concentration as the reference product, the potential for resistance development is not expected to differ between the formulations.

The SPC includes appropriate information on how to minimise the risk of selection of antimicrobial resistance as well as relevant warnings about possible cross-resistance across other classes of antimicrobials.

Adequate warnings and precautions appear on the product literature.

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 of the product is favourable.

MODULE 4

POST- AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)

The post-authorisation assessment (PAA) contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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