Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Linco-Spectin SP 100 mg/g Powder for Oral Solution

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Linco-spectin SP 100 mg/g Powder for Oral Solution
Applicant	Zoetis UK Limited 5th Floor, 6 St. Andrew Street, London , EC4A 3AE
Active substance(s)	Lincomycin hydrochloride Spectinomycin sulphate
ATC Vetcode	QJ01FF52
Target species	Pigs and poultry (non-layers)
Indication for use	<u>Pigs:</u> For the treatment and metaphylaxis of porcine proliferative enteropathy (ileitis) caused by *Lawsonia intracellularis*, and associated enteric pathogens (*Escherichia coli*) susceptible to lincomycin and spectinomycin. The presence of the disease in the group must be established before the product is used. <u>Poultry:</u> For the treatment and metaphylaxis of chronic respiratory disease (CRD) caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to lincomycin and spectinomycin, and associated with a low mortality rate. The presence of the disease in the flock must be established before the product is used.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Veterinary Medicines Directorate website (www.vmd.defra.gov.uk)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Informed consent application in accordance with Article 13c of Directive 2001/82/EC as amended.

SCIENTIFIC OVERVIEW

The quality, safety and efficacy aspects of this product are identical to Linco-Spectin 100 Soluble Powder, Powder for Oral Solution. The initial application for Linco-Spectin 100 Soluble Powder, Powder for Oral Solution was assessed before there was a requirement to have a public assessment report; therefore no details in this section are available.

II. 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.

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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