



**Veterinary
Medicines
Directorate**

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

NATIONAL PROCEDURE

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

Cocci-Drench 2.5 mg/ml Oral Suspension

Date Created: December 2019

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Cocci-Drench 2.5 mg/ml Oral Suspension
Applicant	Elanco Europe Ltd
Active substance	Diclazuril
ATC Vetcode	QP51AJ03
Target species	Sheep and Cattle
Indication for use	<p>For the treatment and prevention of coccidial infections in lambs caused in particular by the more pathogenic <i>Eimeria</i> species, <i>Eimeria crandallis</i> and <i>Eimeria ovinoidalis</i>.</p> <p>To aid in the control of coccidiosis in calves caused by <i>Eimeria bovis</i> and <i>Eimeria zuernii</i>.</p>

MODULE 2

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

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MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Informed consent application in accordance with Article 13 (c) of Directive 2001/82/EC, as amended.
Date of conclusion of the procedure	21 st November 2019

I. SCIENTIFIC OVERVIEW

The quality/safety/efficacy aspects of this product are identical to Vecoxan 2.5 mg/ml Oral Suspension.

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 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.

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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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