Veterinary Medicines Directorate

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Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Dicla-cocci 2.5 mg/ml Oral Suspension for Cattle and Sheep

Date Created: November 2025

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Dicla-cocci 2.5 mg/ml Oral Suspension for Cattle and Sheep
Applicant	Huvepharma/Uitbreidingstraat 80 – 2600 Antwerp – Belgium
Active substance	Diclazuril
ATC Vetcode	QP51BC03
Target species	Cattle Sheep
Indication for use	Cattle (calves): Prevention of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii*. Use the veterinary medicinal product during the prepatent period of infection for the prevention of clinical signs. Sheep (lambs): Prevention of coccidiosis caused by *Eimeria crandallis* and *Eimeria ovinoidalis*. Use the veterinary medicinal product during the prepatent period of infection for the prevention of clinical signs.

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 VMRs 2013 (Schedule 1, Para 10) as amended.
Date of conclusion of the procedure	03/09/2025

I. SCIENTIFIC OVERVIEW

This is a generic application with the reference product being Vecoxan 2.5 mg/ml which has been authorised since 1998.

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 SPC[1]. 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 efficacy[2] 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 diclazuril and the excipients methyl parahydroxybenzoate, propyl parahydroxybenzoate, microcrystalline cellulose, carmellose sodium, citric acid, sodium hydroxide, polysorbate 20 and water for injections.

The container/closure system consists of a high-density polyethylene hanging bottle of 250 mL or high-density polyethylene back-pack bottles either of 1 litre or 5 litres. The particulars of the containers and controls performed are provided and conform to the regulation.

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

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

[1] SPC – Summary of Product Characteristics.
[2] Efficacy – The production of a desired or intended result.

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. The manufacturing method consists of dissolution, mixing, filtration and filling.

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 diclazuril, an established active 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 have been provided.

II.C.4. Substances of Biological Origin

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

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 has been provided demonstrating compliance with the specification. Control tests on the finished product are those suitable for this 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

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 3 months.

The product must not be frozen and should be protected from frost.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

Studies have been conducted/bibliographical data has been provided which show that diclazuril is an anticoccidial of the benzeneacetonitrile group without antimicrobial activity and has anticoccidial activity against Eimeria species. Depending on the coccidia species, diclazuril has a coccidiocidal effect on the asexual or sexual stages of the development cycle of the parasite. Diclazuril treatment will only have limited effect on the intestinal lesions caused by parasitic stages older than 16 days. Treatment with diclazuril causes interruption of the coccidial cycle and of excretion of oocysts for approximately 2 weeks. This allows the animal to bridge the period of decrease of maternal immunity (observed at approximately 4 weeks of age).

The applicant has also provided bibliographical data which shows that the absorption of diclazuril in lambs is poor after administration of the oral suspension. Maximum concentrations in plasma are reached about 24 hours after dosing. The absorption decreases with the animals' age. The elimination half-life is about 30 hours. In vitro studies on sheep hepatocytes demonstrated that metabolic transformation of diclazuril is limited. This was equally observed in other animal species. Excretion occurs almost completely via the faeces.

When diclazuril is administered in oral suspension to calves, its absorption is poor.

Toxicological Studies

Not required due to the legal basis of the application.

User Safety

A user risk assessment was provided in compliance with the relevant guideline.

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:

- Esters of parahydroxybenzoic acid may cause allergic reactions (possibly delayed). People with known hypersensitivity to parabens should administer the veterinary medicinal product with caution.
- Wash hands after administration of the veterinary medicinal product.

Environmental Safety

The Environmental Risk Assessment (ERA) was carried out in accordance with VICH and CVMP guidelines.

Phase I:
The initial predicted environmental concentration (PEC) in soil is less than 100 µg/kg. A Phase II ERA was not required.

III.B.2 Residues documentation

Residue Studies

No residue depletion studies were conducted because of the legal basis of this application. The withdrawal periods are the same as those for the reference product.

Maximum residue limits (MRL)

Diclazuril is listed in Table 1 of Regulation 37/2010 with a status of 'No MRL Required' for the target species for this veterinary medicine.

All the excipients used in this veterinary medicine have been classed as food additives and have a valid E numbers under Regulation (EC) 1333/2008 of the European Parliament and the Council on food additives. Therefore, they are approved as additives in foodstuffs for human consumption and no MRLs are required.

Withdrawal Periods

Cattle (calves) and Sheep (lambs):
Meat and offal: Zero days

IV. CLINICAL DOCUMENTATION

Not required due to the legal basis of the application.

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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