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AGENCE NATIONALE DU
MEDICAMENT VETERINAIRE

FRENCH AGENCY FOR FOOD, ENVIRONNEMENTAL AND OCCUPATIONAL HEALTH SAFETY

FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS

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PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Cocciril 2.5 mg/ml oral suspension for cattle and sheep
Cocciril Vet 2.5 mg/ml oral suspension for cattle and sheep

21 May 2025

PRODUCT SUMMARY

EU procedure number	FR/V/0479/001/DC
Name, strength and pharmaceutical form	Cocciril 2.5 mg/ml oral suspension for cattle and sheep Cocciril Vet 2.5 mg/ml oral suspension for cattle and sheep Dicla-cocci 2.5 mg/ml oral suspension for cattle and sheep
Applicant	HUVEPHARMA / UITBREIDINGSTRAAT 80 – 2600 ANTWERP – BELGIUM
Active substance(s)	Diclazuril
ATC vetcode	QP51BC03
Target species	Cattle (calves) and sheep (lambs)
Indication for use	Cattle (calves): Prophylaxis of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii*. Sheep (lambs): Prophylaxis 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.

PRODUCT INFORMATION

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).

SUMMARY OF ASSESSMENT

Legal basis of original application*	Generic application in accordance with Article 18 of Regulation (EC) 2019/6 as amended.
Reference product (RP)	Vecoxan 2.5 mg/mL Oral Suspension
Marketing authorisation holder	INTERVET
MS where the RP is or has been authorised	France
Marketing authorisation number EU procedure number	FR/V/5395150 6/1998 (France) FR/V/0113/001/MR
Date of authorisation	20/07/1998
Date of completion of the original decentralised procedure	30 April 2025
Concerned Member States for original procedure	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LV, LU, MT, NL, NO, PL, PT, RO, SE, SI, SK, UK(NI).

*Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES

1. 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.

2. QUALITY DOCUMENTATION

A. Product description

The VMP contains 2.5 mg/mL of diclazuril and the excipients methyl parahydroxybenzoate, propyl parahydroxybenzoate, microcrystalline cellulose and carmellose sodium, citric acid, sodium hydroxide, polysorbate and water for injections.

The container/closure systems are high-density polyethylene bottles closed with polypropylene screw cap with a polyethylene-lined sealing disk (wadding) for induction sealing inside.

The choice of the presence of preservative is justified.

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

B. Description of the manufacturing method

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

Process validation data on the VMP have been presented in accordance with the relevant European guidelines.

C. Production and control of starting materials

The active substance is diclazuril, an established active substance described in the European Pharmacopeia. 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.

Certificate of suitability issued by the EDQM has 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.

D. Control tests carried out on isolated intermediates during the manufacturing process

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 VMP.

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.

F. Stability tests

A re-test period is specified in the CEP of the active substance.

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

The in-use shelf life after opening of VMP is supported by the data provided.

G. Other information

Not applicable.

3. SAFETY DOCUMENTATION (safety and residues tests)

A. Safety tests

Pharmacological studies

See part 4.

Toxicological studies

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and essential similarity to a reference VMP has been demonstrated, results of toxicological studies are not required.

Other studies

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and essential similarity to a reference VMP has been demonstrated, results of other studies are not required.

User safety

The safety aspects of this VMP are identical to the reference VMP.

Warnings and precautions as listed on the product literature are almost the same as those of the reference VMP and are adequate to ensure safety of the product to users of the VMP. An additional warning sentence for the user was included in the SPC due to potential hypersensitivity reactions of the excipients methyl parahydroxybenzoate and propyl parahydroxybenzoate.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

Phase I:

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the initial predicted environmental concentration in soil (PECsoil, initial = 5.7 µg/kg) is less than 100 µg/kg.

Warnings and precautions as listed on the product literature are the same as those of the reference VMP and are adequate to ensure safety of the product to the environment.

B. Residues documentation

Residue tests

No residue depletion studies were conducted because it is a generic application for oral administration.

Maximum Residue Limits

Diclazuril is included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 as follows:

Marker residue	Animal species	MRLs(µg/kg)	Target species	Other provisions
Not applicable	All ruminants, porcine	No MRL required	Not applicable	For oral use only.
Diclazuril	Poultry	500 µg/kg 500 µg/kg 1500 µg/kg 1000 µg/kg	Muscle Skin+ fat Liver Kidney	Not for use in animals from which eggs are produced for human, consumption
	Rabbit	150 µg/kg 300 µg/kg 2500 µg/kg 1000 µg/kg	Muscle Fat Liver Kidneys	

Withdrawal Periods

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and essential similarity to the reference VMP has been demonstrated and as the two products are orally administered at the same dose and to the same target species, the same withdrawal period approved for the reference product can apply to the candidate product, Cocciril 2.5 mg/mL oral suspension for cattle and sheep, as follows:

Cattle (calves) and sheep (lambs)
Meat and offal: zero days

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

A. Pre-Clinical Studies

Pharmacology

This is a generic application according to Article 18 of Regulation (EU) 2019/6. The product has the same pharmaceutical form as the reference VMP Vecoxan 2.5 mg/mL Oral Suspension, the same qualitative and quantitative composition of active substance. The essential similarity between the products has been satisfactorily demonstrated. Consequently, as details on pharmacology in the target species, have been sufficiently described in the file of the reference VMP, no further documentation was needed.

Development of resistance and related risk in animals

The current resistance situation against the active substance was documented. Adequate warnings and precautions appear on the product literature.

Dose determination and confirmation

No dose determination and confirmation studies were performed.
As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and essential similarity to the reference VMP has been demonstrated, efficacy studies are not required.
The efficacy claims for this VMP are equivalent to those of the reference VMP.

Tolerance in the target species of animals

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and essential similarity to the reference VMP has been demonstrated, tolerance studies are not required.
The product literature accurately reflects the type and incidence of adverse effects, which might be expected in both target species, calves and lambs.

B. Clinical trials

No clinical trials were performed.

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and essential similarity to the reference VMP has been demonstrated, efficacy studies are not required.
The efficacy claims for this VMP are equivalent to those of the reference VMP.

5. 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.