FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS
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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Coccibal 400 mg/ml solution for use in drinking water for chickens and turkeys

DATE: 08/01/2021

MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0230/002/DX/001
Name, strength and pharmaceutical form	Coccibal 400 mg/ml solution for use in drinking water for chickens and turkeys
Applicant	SP VETERINARIA SA Ctra Reus Vinyols km 4.1 Riudoms (43330) Spain
Active substance(s)	Amprolium
ATC Vetcode	QP51AX09
Target species	Chickens (broilers, pullets, layers, breeder hens) and turkeys
Indication for use	Treatment of intestinal coccidiosis caused by Eimeria spp susceptible to Amprolium.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the website http://www.anmv.anses.fr/

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13(3) of Directive 2001/82/EC as amended.
Date of completion of the decentralised procedure	18/11/2020
Concerned Member States for original procedure	BE, BG, CY, CZ, DE, DK, EL, HU, IE, IT, LU, MT, NL, PL, PT, RO, UK

I. SCIENTIFIC OVERVIEW

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.
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 of the product was demonstrated according to the claims made in the SPC.
The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Composition

The product contains 400,0 mg/mL of amprolium (as hydrochloride) and the following excipients: propyleneglycol, sodium methylparahydroxybenzoate, sodium propylparahydroxybenzoate and purified water.
The packaging of the finished product is as described on the SPC. The particulars of the containers and controls performed are provided and conform to the regulation.
The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.
The product is manufactured using conventional manufacturing techniques. Process validation for full-scale batches will be performed post-authorisation.

C. Control of Starting Materials

The active substance is amprolium hydrochloride, an established active substance described in the British Veterinary 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.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

Scientific data 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.

E. Control on intermediate products

Not applicable.

F. 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.

G. Stability

Stability data on the active substance have been provided in accordance with applicable European 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 European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.
The shelf-life after opening the packaging and the shelf-life after dilution in water as detailed on the SPC has been supported by appropriate data.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

This application is submitted in agreement with the Article 13(3), as hybrid application since the test and reference product NEMAPROL 10.6% ORAL SOLUTION differ by a change in strength (quantitative change to the active substance).
Based on information provided in support of this application, it is accepted that the test product is bioequivalent to the reference product.
The pharmacological aspects of this product are identical to the reference product.

Toxicological Studies

The scope of this application consists of an addition of a new strength of an already approved marketing authorization, Coccibal 200 mg/ml solution for use in drinking water. The new strength (400 mg/ml) does not affect the toxicological profile of amprolium.

The toxicological aspects of this product are identical to the reference product.

User Safety

The applicant has provided a user safety assessment. The user warnings proposed address the identified risks of the product.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

Coccibal 400 mg/ml is intended to be used in the drinking water at the same dose than Coccibal 200 mg/ml. It is accepted that the Environmental Risk Assessment of this VMP is identical to that of Coccibal 200 mg/ml.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted since the tested product is bioequivalent to the reference product and the product is administered via oral route.

MRLs

The active substance, amprolium, is included in table 1 of the MRL regulation 470/2009, as follows:

Pharmacologically active Substance	Marker residue	Animal Species	MRL	Target Tissues	Other Provisions	Therapeutic Classification
AMPROLIUM	Not applicable	poultry	No MRL required	Not applicable	For oral use only	No entry

Withdrawal Periods

The same withdrawal periods as for the reference product are applicable.

Species	Tissues	Withdrawal periods
Chickens and turkeys.	Meat & offal	0 days
	Eggs	0 days

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

Coccibal is intended to be used in the drinking water at the same dose than the princeps product, it can be accepted that the tolerance in the target species of this VMP should not be different to that of the reference product.

Resistance

The applicant has documented the current state of resistance to amprolium. Adequate warnings and precautions appear in the product literature.

IV.B Clinical Studies

Since the tested product and the reference product are bioequivalent and are intended to be used in drinking water to prepare medicated water of the same concentration, it can be concluded that the clinical effects of the two products will be the same and no clinical studies are required.

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 risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.