1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Coccibal, 200 mg/mL solution for use in drinking water for chickens and turkeys

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL contains:

Active substance:
Amprolium ..... 200 mg
(equivalent to 226.2 mg Amprolium Hydrochloride)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium methyl parahydroxybenzoate (E 219)	1 mg
Sodium propyl parahydroxybenzoate	0.2 mg
Propylene glycol	
Purified water	

Clear yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (broilers, pullets, layers, breeder hens) and turkeys.

3.2 Indications for use for each target species

Treatment of intestinal coccidiosis caused by *Eimeria* spp susceptible to amprolium.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

As with any antiparasiticide, frequent and repeated use of antiprotozoal agents of the same class can lead to resistance development.
In case of detection a lack of efficacy during treatment, communicate it to the national competent authorities.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The product is not intended for preventive use.
This product should be reserved for use in case of coccidiosis outbreaks due to non-availability of vaccine, in case of lack of efficacy of vaccine and in vaccinated flocks if a severe coccidial challenge is diagnosed before immunity has fully developed.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

This product is acidic and may cause irritation to, or corrosion of, the skin, eyes, throat and airways.
Avoid all physical contact with the product, including any vapours.
Do not eat, drink or smoke whilst handling this product.
Personal protective equipment consisting of impervious gloves and protective glasses should be worn when handling the veterinary medicinal product. The selected protective gloves should satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.
In the case of contact with skin or eyes, wash the affected area with clean running water immediately and remove any contaminated clothes. If irritation persists, seek medical advice and show the label to the physician.
In case of accidental ingestion, rinse the mouth with fresh water, seek medical advice immediately and show the label to the physician
People with known hypersensitivity to amprolium or to any of the excipients should avoid contact with the product.
Wash hands and exposed skin after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chickens (broilers, pullets, layers, breeder hens) and turkeys.

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lay.

Pregnancy:
Studies in laboratory animals have not produced any evidence of teratogenic effects.
Laying birds:
The safety of amprolium has not been investigated in laying birds.

Use only according to the risk/benefit assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Amprolium is a thiamine analogue. Therefore, the efficacy of amprolium may be reduced during a simultaneous administration of products containing vitamin B-complex.

3.9 Administration routes and dosage

In drinking water use.
Posology for each target species is 20 mg amprolium / kg b.w. a day (corresponding to 1 mL of oral solution / 10 kg of bodyweight / day) for 5-7 consecutive days.
For the preparation of medicated water and to ensure a correct dosage, body weight should be determined as accurately as possible ad their actual daily water consumption should be taken into

account. Consumption may vary depending on factors like age, state of health, breed, husbandry system. To provide the required amount of veterinary medicinal product in mLmL per litre drinking water the following calculation should be made:

$$\frac{\text{0.1 mL of veterinary medicinal product / kg body weight per day} \times \text{average body weight (kg) of animals to be treated} \times \text{number of animals}}{\text{Average daily water intake (l/animal)}} = \text{mL veterinary medicinal product per litre of drinking water}$$

Sufficient access to the system of water supply should be available for the animals to be treated to ensure adequate water consumption. No other source of drinking water should be available during the medication period. Medicated drinking water should be replaced every 24 hours.

After the end of the medication period the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance.

The veterinary medicinal product must not come into contact with metal water pipes or metal containers.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Prolonged uses can produce thiamine deficiencies
This deficiency can be compensated by a thiamine intake.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable

3.12 Withdrawal periods

Chickens and turkeys:
- Meat and offal: zero days.
- Eggs: zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP51BX02.

4.2 Pharmacodynamics

Amprolium is an anticoccidial which belongs to the thiamine analogues family. Amprolium acts by interfering as a competitive antagonist of thiamine within thiamine transport mechanisms. It interferes in the carbohydrate metabolism required for coccidian multiplication and survival.
In in-vitro studies it was shown that the uptake of thiamine by schizonts of Eimeria tenella and by host intestinal cells can occur through passive diffusion or by an active, energy-and ph-dependent process. Amprolium competitively inhibited both systems, however, the parasite was shown to be more sensitive to amprolium than the host.

As shown with Eimeria maxima inoculated chicken, the administration of Amprolium resulted in a proportion of morphologically abnormal macrogametes and oocysts which may be considered the reason for a reduced sporulation rate.

4.3 Pharmacokinetics

After oral administration absorption is low, reaching the maximum concentration 4 hours later. It is excreted mainly through faeces.

Environmental properties

Amprolium is persistent in soil.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing biocidal products, feed additives or other substances used in drinking water.

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal product.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 6 months.
Shelf-life after dilution or reconstitution according to directions: 24 hours.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

100 mL and 1 litre containers: white, opaque high density polyethylene bottles sealed by induction and with screw-on cap.
5 litres container: white, opaque high density polyethylene barrels sealed by induction and with screw-on cap.
Presentations: 1 L, 5 L, 12 x 1 L in cardboard box, 4 x 5 L in cardboard box, 10 x 100 mL in cardboard box with leaflet.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

S.P. VETERINARIA, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10790/012/001

8. DATE OF FIRST AUTHORISATION

16/02/2017

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

25/07/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).