SUMMARY OF PRODUCT CHARACTERISTICS

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 Hydrocloride)

Excipients:

Sodium methyl parahydroxybenzoate (E219) 1 mg
Sodium propyl parahydroxybenzoate 0.2 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for use in drinking water.

Clear yellow solution

4. CLINICAL PARTICULARS

4.1 Target species

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

4.2 Indications for use, specifying the target species

Chickens (broilers, pullets, layers, breeder hens) and turkeys: treatment of intestinal coccidiosis caused by *Eimeria* spp susceptible to amprolium.

4.3 Contraindications

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

4.4 Special warnings for each target species

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

4.5 Special precautions for use

Special precautions for use in animals

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.
Wear impervious gloves and protective glasses when handling the 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
Those with known hypersensitivity to amprolium or to any of the excipients should avoid contact with the product.
Wash hands and exposed skin after use.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

Studies in laboratory animals have not produced any evidence of teratogenic effects. The safety of amprolium has not been investigated in laying birds. Use only according to the risk/benefit assessment by the responsible veterinarian.

4.8 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.

4.9 Amounts to be administered and administration route

In drinking water use.
Posology for each target species is 20 mg amprolium / kg b.w. a day for 5-7 consecutive days
For the preparation of medicated water the body weight of the animals to be treated and 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 ml per litre drinking water the following calculation should be made:

$$\frac{\text{0.1 ml the product per kg bodyweight daily} \times \text{average bodyweight (kg) of the animals to be treated} \times \text{number of animals}}{\text{Total water consumption (l) of the herd at the previous day drinking water}} = \text{ml the product per litre}$$

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Prolonged uses can produce thiamine deficiencies

In cases of deficiency, thiamine must be administered to compensate for this.

4.11 Withdrawal period(s)

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antiprotozoals; agents against protozoal disease, amprolium
ATCvet code: QP51AX09.

5.1 Pharmacodynamic properties

Amprolium is an anticoccidial agent that acts as competitive inhibitor of thiamine in the parasite metabolism and interferes with the metabolism of glucides necessaries 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.

5.2 Pharmacokinetic particulars

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol
Sodium methyl parahydroxybenzoate (E219)
Sodium propyl parahydroxybenzoate
Purified water

6.2 Incompatibilities

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

6.3 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

6.4 Special precautions for storage

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

6.5 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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements

7. MARKETING AUTHORISATION HOLDER

SP Veterinaria, S.A.
Ctra. Reus-Vinyols, Km 4.1
43330 Riudoms
Spain

8. MARKETING AUTHORISATION NUMBER

36967/4001

9. DATE OF FIRST AUTHORISATION

11 April 2012

10. DATE OF REVISION OF THE TEXT

February 2023

Approved 09 February 2023