Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:
Amprolium 400 mg
(equivalent to 452.4 mg Amprolium Hydrochloride)

Excipients:
Sodium methyl parahydroxybenzoate (E-219) 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 yellowish 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

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

4.3 Contraindications

Do not use in known cases 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 antiprotozoal agents of the same class can lead to resistance development.
In case of detection of 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.
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.

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 interactions

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 bodyweight a day (corresponding to 0.5 ml of oral solution / 10 kg of bodyweight / 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:

$$\frac{0{,}05\ ml\ product\ /_{kg\ bodyweight}\ X\ average\ bodyweight\ (kg) animals\ to\ be\ treated\ X\ \ n^{o}\ animals}{total\ water\ consumption\ (L)\ of\ the\ herd\ at\ the\ previous\ day} = ml\ product\ /_{L\ drinking\ water}$$

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.
The highest nominal concentration of the solution in drinking water is 54 ml/L. 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 container.

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

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

4.11 Withdrawal period(s)

Chickens:	Meat and offal:	Zero days
	Eggs:	Zero days
Turkeys:	Meat and offal:	Zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

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

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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

5.3 Environmental properties

Amprolium is persistent in soil.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol
Sodium methyl parahydroxybenzoate (E-219)
Sodium propyl parahydroxybenzoate
Purified water

6.2 Major 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 according to directions: 24 hours

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and composition of immediate packaging

100 ml and 1 litre containers: white, opaque high density polyethylene bottles sealed by induction with multilayered disk (Foil, PET and HDPE, where HDPE is in contact with the product) and with green, high density polyethylene screw cap.
5 litres container: white, opaque high density polyethylene barrels sealed by induction with multilayered disk (Foil, PET and HDPE, where HDPE is in contact with the product) and with green, high density polyethylene screw cap.
Presentations: 100 ml, 1 L, 5 L
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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
Riudoms 43330
Spain

8 MARKETING AUTHORISATION NUMBER(S)

VPA10790/012/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26 February 2021

10 DATE OF REVISION OF THE TEXT