PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Label for 100 mL box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Coccibal 400 mg/mL solution for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Each mL contains:

Amprolium.....400 mg
(equivalent to 452.4 mg Amprolium Hydrochloride)

3. PACKAGE SIZE

100 mL

4. TARGET SPECIES

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

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 6 months.
Once opened use by…

9. SPECIAL STORAGE PRECAUTIONS

Store below 30º C.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

SP Veterinaria, S.A.

14. MARKETING AUTHORISATION NUMBERS

Vm 36967/4009

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label for 1 L without box, 5 L without box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Coccibal 400 mg/mL solution for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Each mL contains:

Amprolium.....400 mg
(equivalent to 452.4 mg Amprolium Hydrocloride)

3. PACKAGE SIZE

1 L.
5 L.

4. TARGET SPECIES

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

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 6 months.
Once opened use by…

9. SPECIAL STORAGE PRECAUTIONS

Store below 30º C.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

SP Veterinaria, S.A.

14. MARKETING AUTHORISATION NUMBERS

Vm 36967/4009

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label for 100 mL with box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Coccibal 400 mg/mL solution for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Each mL contains:

Amprolium.....400 mg
(equivalent to 452.4 mg Amprolium Hydrochloride)

3. TARGET SPECIES

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

4. ROUTES OF ADMINISTRATION

In drinking water use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

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

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 6 months.
Once opened use by…

7. SPECIAL STORAGE PRECAUTIONS

Store below 30º C.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

SP Veterinaria, S.A.

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. 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

Clear yellowish solution.

3. Target species

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

4. Indications for use

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

5. Contraindications

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

6. Special warnings

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.

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 gloves and protective 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.

Pregnancy:

Studies in laboratory animals have not produced any evidence of teratogenic effects.
The safety of the veterinary medicinal product has not been established during pregnancy and lay.

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.

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.

Overdose:

Prolonged uses can produce thiamine deficiencies.

This deficiency can be compensated by a thiamine intake.

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.

7. Adverse events

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

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at https://www.gov.uk/report-veterinary-medicine-problem.

8. Dosage for each species, routes and method of administration

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:

mLmL

$$\frac{\text{0.05 mL of veterinary medicinal product / kg body weight per day} \times \text{average body weight (kg) of animals to be treated} \times \text{number of animals}}{\text{Average daily water intake (l/animal)}} = \text{mL veterinary medicinal product per litre of drinking water}$$

9. Advice on correct administration

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 containers.

10. Withdrawal periods

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

11. Special storage precautions

Keep out of the sight and reach of children.

Store below 30° C.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf-life after first opening the immediate packaging: 6 months.
Shelf-life after dilution or reconstitution according to directions: 24 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 36967/4009

Package sizes: 100 ml, 1 L and 5 L.
Presentations: 1 L, 5 L, 1 x 100 mL in cardboard box with leaflet.
Not all pack sizes may be marketed.

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
SP Veterinaria, S.A.
Ctra. Reus-Vinyols, km 4,1
43330 Riudoms (Spain)
Tel. +34 977 850 170

Local representatives and contact details to report suspected adverse reactions:

Vetsonic (UK) Ltd.
Riccal Drive, York Road Business Park,
MALTON, YO17 6YE, UK
Tel: +44 7887 420538

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V	Veterinary medicinal product subject to prescription

Environmental properties

Amprolium is persistent in soil.

Gavin Hall
Approved: 14 October 2025