PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml and outer package

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Coccibal, 200 mg/ml solution for use in drinking water for chickens and turkeys
Amprolium(as hydrochloride)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Amprolium 200 mg
(equivalent to 226.2 mg Amprolium Hydrocloride)
Sodium methyl parahydroxybenzoate (E219) 1 mg
Sodium propyl parahydroxybenzoate 0.2 mg

3. PHARMACEUTICAL FORM

Solution for use in drinking water.

Clear yellow solution

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

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

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

<EXP {month/year}>
Once opened, use by…>
Shelf-life after first opening the immediate packaging: 6 months
BOX PL: Termin ważności (EXP)

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

PL: Wyłącznie dla zwierząt. Wydawany z przepisu lekarza – Rp

Do podawania pod nadzorem lekarza weterynarii

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

SP VETERINARIA SA
Ctra Reus Vinyols km 4.1
Riudoms (43330)
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 36967/4001

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}
BOX PL: Nr serii (Lot)

Label for: 1 L and 5 L

Coccibal, 200 mg/ml solution for use in drinking water for chickens and turkeys
Amprolium(as hydrochloride)

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer:

SP VETERINARIA SA
Ctra Reus Vinyols km 4.1
Riudoms (43330)
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Coccibal, 200 mg/ml solution for use in drinking water for chickens and turkeys
Amprolium(as hydrochloride)

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml of the clear yellow solution contains:

Amprolium 200 mg
(equivalent to 226.2 mg Amprolium Hydrocloride)

Excipients:

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

4. INDICATION(S)

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

Non known.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

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

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions

Shelf-life after first opening the container: 6 months

Shelf-life after dilution or reconstitution according to directions: 24 hours

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

Do not use this veterinary medicinal product after the expiry date stated on the label.

12. SPECIAL WARNING(S)

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.

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.

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.

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 (symptoms, emergency procedures, antidotes), if necessary

Prolonged uses can produce thiamine deficiencies

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

Incompatibilities

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Not all pack sizes may be marketed.

Package size: 100 ml, 1 L and 5 L
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
Expiry date:
PL: Termin ważności (EXP)
For animal treatment only - to be supplied only on veterinary prescription.
PL: Wyłącznie dla zwierząt. Wydawany z przepisu lekarza – Rp

Do podawania pod nadzorem lekarza weterynarii

MARKETING AUTHORISATION NUMBER(S)

EU/0/00/000/000

MANUFACTURER'S BATCH NUMBER

Once opened, use by …
Shelf-life after dilution or reconstitution according to directions: 24 hours

<Batch> <Lot> <BN> {number}

PACKAGE LEAFLET

Leaflet for 100 ml

Coccibal, 200 mg/ml solution for use in drinking water for chickens and turkeys
Amprolium(as hydrochloride)

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer:

SP VETERINARIA SA
Ctra Reus Vinyols km 4.1
Riudoms (43330)
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Coccibal, 200 mg/ml solution for use in drinking water for chickens and turkeys
Amprolium(as hydrochloride)

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml of the clear yellow solution 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

4. INDICATION(S)

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

None known
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

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8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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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.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions

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

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.
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Approved 20 April 2017