

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml and outer package

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Amprolium 200 mg
(equivalent to 226.5 mg Amprolium Hydrochloride)

Excipients

Sodium methyl parahydroxybenzoate (E219)	1 mg
Sodium propyl parahydroxybenzoate (E217)	0.2 mg

3. PHARMACEUTICAL FORM

Solution for use in drinking water
Clear yellow solution

4. PACKAGE SIZE

100 ml, 1 L and 5 L

5. TARGET SPECIES

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

6. INDICATIONS

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

7. METHOD AND ROUTES OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNINGS, IF NECESSARY

See package leaflet for full instructions, including user warnings

10. EXPIRY DATE

<EXP {month/year}>
Once opened, use by...>
Shelf-life after first opening the immediate packaging: 6 months

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.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Global Vet Health S.L.
C/Capcanes
Nº 12-bajos
Polígono Agro-Reus
Reus 43206
Spain

16. MARKETING AUTHORISATION NUMBER

Vm 36167/4002

17. MANUFACTURER'S BATCH NUMBER

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

A handwritten signature in black ink, consisting of several vertical strokes followed by a horizontal line that curves upwards and to the right.

Approved 01 February 2017

Label for: 1 L and 5 L

EIMERYL , 200 mg/ml solution for use in drinking water for chicken 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

Global Vet Health S.L.
C/Capcanes
Nº 12-bajos
Polígono Agro-Reus
Reus 43206
Spain

Manufacturer responsible for batch release:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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4. INDICATIONS

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

5. CONTRAINDICATIONS

None known

6. ADVERSE REACTIONS

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, ROUTES 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:

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

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.

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

Do not use after the expiry date stated on the label

12. SPECIAL WARNINGS

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 a preventive use.

This product should be reserved 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.

User warnings

This is an irritant and corrosive product. It could cause airway, eye and skin irritation. Wear impervious gloves and protective glasses when handling the product.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Avoid inhalation of vapours.

Avoid contact with the skin and eyes. 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 package leaflet to the doctor.

This product is harmful when ingested. In case of accidental ingestion, rinse the mouth with fresh water, seek medical advice immediately and show the label to the doctor.

Person with known hypersensitivity to the active substance or to any of 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)

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

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14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Not all pack sizes may be marketed.

Once opened, use by ...

Package size: 100 ml, 1 L and 5 L

Presentations: 1 L, 5 L, 12 x 1 L in cardboard box and 4 x 5 L in cardboard box, 10 x 100 ml in cardboard box with leaflet

Expiry date:

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

MARKETING AUTHORISATION NUMBER(S)

EU/0/00/000/000

MANUFACTURER'S BATCH NUMBER

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

PACKAGE LEAFLET

Leaflet for 100 ml

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