COMBINED LABEL AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE – COMBINED LABEL AND PACKAGE LEAFLET

100 mL, 1 L and 5 L HDPE cans

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

Marketing authorization holder and manufacturer responsible for batch release:
HUVEPHARMA SA
34 rue Jean Monnet
Z.I. d'Etriché
Segré
49500 Segré-en-Anjou Bleu
France

Or

Marketing authorization holder
HUVEPHARMA SA
34 rue Jean Monnet
Z.I. d'Etriché
Segré
49500 Segré-en-Anjou Bleu
France

Manufacturer responsible for batch release:
Biovet Joint Stock Company
39 Petar Rakov Str.
4550 Peshtera
Bulgaria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

AMPROLINE 400 mg/mL solution for use in drinking water for chickens and turkeys
Active substance: amprolium (as hydrochloride)

3. STATEMENT OF ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each mL contains:

Active substance:
Amprolium…….400.0 mg
(equivalent to 452.4 mg of amprolium hydrochloride)

Excipients:
Preservative: sorbic acid (E200)…… .0.5 mg

4. PHARMACEUTICAL FORM

Solution for use in drinking water
Clear and yellow solution

5. PACKAGE SIZE

100 mL
1 L
5 L

6. INDICATION(S)

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

7. CONTRAINDICTIONS

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

8. ADVERSE REACTIONS

None known.
Alternatively you can report via your national reporting system {national system details}.

9. TARGET SPECIES

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

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

For use in drinking water.
The posology for each target species is 20 mg amprolium / kg body weight / day (equivalent to 0.5 mL of oral solution / 10 kg bodyweight/day) for 5 to 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, and husbandry system. To provide the required amount of veterinary medicinal product in ml per litre drinking water the following calculation should be made:

0.05 mL of the product per kg bodyweight X average bodyweight (kg) of the animals to be daily treated X number of animals
---------- = mL of oral solution / Litre of drinking water

Total water consumption (L) of the herd at the previous day

11. 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.

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 should not be used in contact with metal pipework or containers.

12. WITHDRAWAL PERIOD(S)

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

13. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C.
Do not use this veterinary medicinal product after the expiry date which is stated on the can. The expiry date refers to the last day of that month.

14. SPECIAL WARNING(S)

Special warnings for each target species
As with any antiparasiticide, frequent and repeated use of antiprotozoal agents from the same class can lead to resistance development.
As with all anticoccidials, prolonged use may result in the development of resistant strains. Use of anticoccidial drugs having the same mode of action should be avoided due to the development of cross-resistance.
In case of lack of efficacy detection 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.

Special precautions to be taken by the person administering the 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 sorbic acid should avoid contact with the product.
Wash hands and exposed skin after use.

Other precautions

Amprolium is very persistent in soil.

Lay

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

Interaction with other medicinal product 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)

A prolonged use at high doses can induce thiamine deficiency. This deficiency can be compensated for by an appropriate thiamine intake.

Incompatibilities

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

15. 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.

16. DATE ON WHICH THE LABEL WAS LAST APPROVED

February 2021

17. OTHER INFORMATION

100 mL can
1 L can
5 L can

Not all pack size may be marketed.

18. 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.

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

Keep out of the sight and reach of children.

20. EXPIRY DATE

EXP: month/year
Shelf life after first opening the immediate packaging: 4 months
Shelf life after dilution according to directions: 24 hours

21. MARKETING AUTHORISATION NUMBER(S)

Vm 41623/4001

22. MANUFACTURER’S BATCH NUMBER

Batch number:

Approved: 08/04/21