A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
100 mL, 1 L and 5 L HDPE cans

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each mL contains:

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

3. PACKAGE SIZE

100 mL
1 L
5 L

4. TARGET SPECIES

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

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

EXP
Once opened: 4 months
Once diluted: 24 hours

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C.

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

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.
To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

HUVEPHARMA SA

14. MARKETING AUTHORISATION NUMBERS

Vm 41623/3000

17. BATCH NUMBER

Batch

B. PACKAGE LEAFLET (=COMBINED LABEL AND PACKAGED LEAFLET)

100 mL, 1 L and 5 L cans

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Each mL contains:

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

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

Clear and yellow solution

3. PACKAGE SIZE

100 mL
1 L
5 L

4. TARGET SPECIES

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

5. INDICATIONS FOR USE

Indications for use
Treatment of intestinal coccidiosis caused by *Eimeria* spp.

6. CONTRAINDICATIONS

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

7. SPECIAL WARNING(S)

Special warnings

Special warnings
As with any antimicrobial, frequent and repeated use of antiprotozoal agents of the same class can lead to resistance development.

Cross-resistance has been shown between amprolium and anticoccidial drugs having the same mode of action.
Use of the veterinary medicinal product/amprolium should be carefully considered when susceptibility testing has shown resistance to amprolium/anticoccidials because its effectiveness may be reduced. As with all anticoccidials, prolonged use may result in the development of resistant strains.
In case of detection of lack of efficacy during treatment, communicate it to the national competent authorities.

Special precautions for safe use in the target species

The veterinary medicinal product is not intended for prophylaxis.
This veterinary medicinal 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.
Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level. Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

This veterinary medicinal product is acidic and may cause irritation to, or corrosion of, the skin, eyes, throat and airways.
Avoid all physical contact with the veterinary medicinal product, including any vapours.
Do not eat, drink or smoke whilst handling this veterinary medicinal product.
Wear impervious gloves and protective glasses 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 sorbic acid should avoid contact with the veterinary medicinal product.
Wash hands and exposed skin after use.

Special precautions for the protection of the environment

Amprolium is classified as a very persistent substance in soil.

Laying birds

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

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

8. ADVERSE EVENTS

Chickens, 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 on this label, 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 using the contact details on this label, or via your national reporting system {national system details}.

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

Dosage for each species, routes 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 veterinary medicinal product / 10 kg bodyweight/day) for 5 to 7 consecutive days.

To ensure a correct dosage, body weight should be determined as accurately as possible.
The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of amprolium may need to be adjusted accordingly.
Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

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

10. ADVICE ON CORRECT ADMINISTRATION

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.

11. WITHDRAWAL PERIOD(S)

Withdrawal periods

Chickens and turkeys

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

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

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

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
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.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 41623/3000

Pack sizes
100 mL can
1 L can
5 L can

Not all pack size may be marketed.

Detailed information on this veterinary medicinal product is available in the Union Product Database *(https://medicines.health.europa.eu/veterinary).*

16. DATE ON WHICH THE LABEL WAS LAST REVISED

November 2023

17. CONTACT DETAILS

Contact details

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

or

Biovet Joint Stock Company
39 Petar Rakov Str.
4550 Peshtera
Bulgaria

Local representatives or contact details to report suspected adverse reactions:

18. OTHER INFORMATION

Amprolium is very persistent in soil.

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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. BATCH NUMBER

Batch number:

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

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2. COMPOSITION

Each mL contains:

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

Clear and yellow solution

3. PACKAGE SIZE

100 mL
1 L
5 L

4. TARGET SPECIES

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

5. INDICATIONS FOR USE

Indications for use
Treatment of intestinal coccidiosis caused by *Eimeria* spp.

6. CONTRAINDICATIONS

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

7. SPECIAL WARNING(S)

Special warnings

Special warnings
As with any antimicrobial, frequent and repeated use of antiprotozoal agents of the same class can lead to resistance development.
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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 veterinary medicinal product.
Wash hands and exposed skin after use.

Special precautions for the protection of the environment
Amprolium is classified as a very persistent substance in soil.

Laying birds
Laboratory studies 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.

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Overdose
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Chickens, turkeys:
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Average daily water intake (L/animal)				

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11. WITHDRAWAL PERIOD(S)

Withdrawal periods

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12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

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16. DATE ON WHICH THE LABEL WAS LAST REVISED

November 2023

17. CONTACT DETAILS

Contact details

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

Or

Biovet Joint Stock Company
39 Petar Rakov Str.
4550 Peshtera
Bulgaria

Local representatives and contact details to report suspected adverse reactions:

18. OTHER INFORMATION

Amprolium is very persistent in soil.

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Approved 18 May 2024