PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
HDPE Bottle labels

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AMPROL 12% w/v Solution for use in drinking water
amprolium hydrochloride

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml solution contains 120mg Amprolium hydrochloride (Equivalent to 106mg Amprolium), 1mg Sorbic acid(E200).

3. PHARMACEUTICAL FORM

Solution for use in drinking water

4. PACKAGE SIZE

1 litre
5 litres

5. TARGET SPECIES

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

6. INDICATION(S)

For the treatment of intestinal coccidiosis caused by Eimeria spp susceptible to amprolium.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use
Oral administration via drinking water.
The target dose is 20 mg amprolium per kg bodyweight per day (approximately equivalent to 2ml of product per 10 kg bodyweight) for 5 to 7 days.

8. WITHDRAWAL PERIOD(S)

Chickens (broilers, pullets, layers, breeder hens)
Meat and offal: Zero days
Eggs: Zero days
Turkeys
Meat and Offal: Zero Days

9. SPECIAL WARNING(S), IF NECESSARY

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 leaflet or the label 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 package leaflet or label to the doctor.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 12 weeks
Shelf life after dilution according to directions: 24 hours
Once opened use by ……..

11. SPECIAL STORAGE CONDITIONS

Medicated drinking water should be replaced every 24 hours

12. SPECIFIC 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.

POM-V

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

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

PHARMSURE INTERNATIONAL LTD. Unit 28, Moorlands Trading Estate, Moor Lane, Metheringham, Lincolnshire. LN4 3HX.

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42983/4000

17. MANUFACTURER’S BATCH NUMBER

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

PACKAGE LEAFLET FOR:
Amprol 12% w/v Solution for use in drinking water

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

Marketing authorisation holder: PHARMSURE INTERNATIONAL LTD. Unit 28, Moorlands Trading Estate, Moor Lane, Metheringham, Lincolnshire. LN4 3HX.
Manufacturer responsible for batch release: MERIAL, 23 rue du Prieuré, 44150 SAINT-HERBLON, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amprol 12% w/v Solution for use in drinking water
amprolium hydrochloride

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

1 ml solution contains 120mg Amprolium hydrochloride (Equivalent to 106mg Amprolium), 1mg Sorbic acid(E200).
Clear, yellow solution

4. INDICATION(S)

For the treatment of intestinal coccidiosis caused by Eimeria spp susceptible to amprolium.

5. CONTRAINDICATIONS

Do not use in cases of known hypersensitivity to the active substance or 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

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

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

For oral administration via drinking water.

The target dose is 20 mg amprolium per kg bodyweight per day (approximately equivalent to 2ml of product per 10 kg bodyweight) for 5 to 7 days. Dilute into

drinking water based on the animals' water consumption requirements over a 24 hour period to obtain the correct dosage (mg/kg).

9. ADVICE ON CORRECT ADMINISTRATION

Gentle mixing is required. Renew the medicated water every 24 hours. No other source of drinking water should be available during the medication period.
The medicinal product should not be used in contact with metal pipework or containers.

10. WITHDRAWAL PERIOD(S)

Chickens (broilers, pullets, layers, breeder hens)
Meat and offal: Zero days
Eggs: Zero days
Turkeys
Meat and Offal: Zero Days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
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: 12 weeks
Shelf life after dilution according to directions: 24 hours
When the bottle is opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the bottle should be discarded should be determined. This discard date should be written in the space provided.

12. SPECIAL WARNING(S)

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.
The adverse effects of amprolium at high doses are caused by thiamine deficiency. Such deficiency can be compensated for by increasing thiamine intake.
Prolonged use can cause thiamine deficiencies. Should symptoms appear, thiamine should be supplemented.
For Animal Treatment Only

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 leaflet or the label 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 package leaflet or label to the doctor.

Environmental properties: Amprolium is persistent in soil.

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

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

June 2016

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

15. OTHER INFORMATION

Amprolium is a thiamine analogue. Therefore, the efficacy of amprolium may be reduced during the simultaneous administration of products containing vitamin B complex.

1 litre
5 litres
Not all pack sizes may be marketed.

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

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Vm number: 42983/4000

Approved: 07/07/2016