SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml solution contains:

Qualitative composition	Quantitative composition
Amprolium hydrochloride	120 mg (equivalent to 106 mg amprolium)
Sorbic acid (E200)	1 mg

3. PHARMACEUTICAL FORM

Solution for use in drinking water
The solution is clear, yellow in colour.

4. CLINICAL PARTICULARS

4.1 Target species

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

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

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

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

i) 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.

ii) Special precautions for the person administering the veterinary medicinal product to animals

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.

iii) Other precautions

None

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 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.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amount(s) to be administered and administration route

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).

Gentle mixing is required. Renew 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

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

Turkeys
Meat and Offal: Zero Days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:
Antiparasitic products, other antiprotozoal agents

ATC Vet Code:
QP51AX09

5.1 Pharmacodynamic properties

Amprolium hydrochloride is a coccidiostat belonging to the thiamine (Vitamin B_1) analogue group. It acts as a competitive antagonist of thiamine transport mechanisms
Amprolium affects coccidia by competing with thiamine in their metabolic enzyme system, thus interfering with metabolism of carbohydrates necessary for multiplication or survival of coccidia

5.2 Pharmacokinetic properties

Amprolium is poorly absorbed after oral administration. Plasma concentration reaches its maximum after 4 hours.

5.3 Environmental properties

Amprolium is persistent in soil.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbic acid (E 200)
Purified water

6.2 Incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: 12 weeks
Shelf life after dilution according to directions: 24 hours

6.4 Special precautions for storage

Medicated drinking water should be replaced every 24 hours

6.5 Nature and composition of immediate packaging

High density polyethylene bottles of 1 litre and 5 litre, closed with a polyethylene screw cap with integral heat seal liner

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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

7. MARKETING AUTHORISATION HOLDER

Pharmsure International Ltd
Unit 28, Moorlands Trading Estate
Moor Lane
Metheringham
Lincolnshire
LN4 3HX

8. MARKETING AUTHORISATION NUMBER(S)

Vm 42983/4000

9. DATE OF FIRST AUTHORISATION

14 June 2016

10. DATE OF REVISION OF THE TEXT

July 2016

Approved: 07/07/2016