Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One mL of solution contains:

Active substance:

Amprolium (as hydrochloride)	400.0	mg
(equivalent to amprolium hydrochloride)	452.0	mg

Excipients:

Sorbic acid (E200)	0.5	mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for use in drinking water.
Limpid and yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

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

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

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

4.4 Special warnings for each target species

As with any antiparasiticide, frequent and repeated use of an antiprotozoal agent of the same class can lead to resistance development.
In case of detection of lack of efficacy during treatment, communicate it to competent national authorities.

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 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
Those with known hypersensitivity to amprolium or to sorbic acid should avoid contact with the product.
Wash hands and exposed skin after use.

iii) Other precautions
Amprolium is classified as a very persistent substance in soil.

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 established in laying birds. Use only according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interactions

Amprolium is an anticoccidial belonging to thiamin analogs family. Therefore, the efficacy of amprolium may be reduced during a simultaneous administration of products containing vitamin B-complex.

4.9 Amounts to be administered and administration route

In drinking water use.
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:

$$\frac{\text{0.05 mL of the product per kg bodyweight} \times \text{average bodyweight (kg) of the animals to be daily treated} \times \text{number of animals}}{\text{Total water consumption (L) of the herd at the previous day}} = \text{mL of oral solution / Litre of drinking water}$$

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.

The veterinary medicinal product should not be used in contact with metal pipework or containers.

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

A prolonged use at high doses can produce thiamine deficiency. This deficiency can be compensated by a thiamine intake.

4.11 Withdrawal period(s)

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: antiprotozoals, agents against protozoal diseases, amprolium.
ATCvet code: QP51AX09.

5.1 Pharmacodynamic properties

Amprolium is an anticoccidial which belongs to the thiamine analogues family. Amprolium acts by interfering as a competitive antagonist of thiamine within thiamine transport mechanisms. It interferes in the carbohydrate metabolism required for coccidies multiplication and survival.

In *in-vitro* studies it was shown that the uptake of thiamine by schizonts of *Eimeria tenella* and by host intestinal cells can occur through passive diffusion or by an active, energy-and pH-dependent process. Amprolium competitively inhibited both systems, however, the parasite was shown to be more sensitive to amprolium than the host.

As shown with *Eimeria maxima* inoculated chicken, the administration of Amprolium resulted in a proportion of morphologically abnormal macrogametes and oocysts which may be considered the reason for a reduced sporulation rate.

5.2 Pharmacokinetic particulars

Amprolium is weakly absorbed after oral administration. Maximum plasma drug concentration is reached 4 hours later. Amprolium is excreted mainly via faeces.

5.3. Environmental properties

Amprolium is very persistent in soil.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbic acid (E200)
Purified water

6.2 Major 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:	24 months
Shelf life after first opening the immediate packaging:	4 months
Shelf life after dilution according to directions:	24 hours

6.4 Special precautions for storage

100 mL and 5 L cans: This veterinary medicinal product does not require any special storage conditions.
1 L can: Do not store above 30°C.

6.5 Nature and composition of immediate packaging

100 mL can: white and opaque can made of high density polyethylene, closed with a white and opaque cap made of high density polyethylene with a ring and having polyethylene foam inside.
1 and 5 L cans: white and opaque can made of high density polyethylene closed with a purple and opaque cap made of polypropylene and having a tamper-proof ring and a seal made of aluminium/PET/polyethylene.

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

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

HUVEPHARMA SA
34 RUE JEAN MONNET
ZI D'ETRICHE
SEGRE
49500 SEGRE-EN-ANJOU BLEU
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA10453/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30 August 2019

10 DATE OF REVISION OF THE TEXT