SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SURRICOXX 400 mg/mL Solution for use in drinking water for chickens, turkeys, ducks, and guinea fowls

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL contains:

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

Excipients:
Benzyl alcohol (E1519).....9 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for use in drinking water.
Clear yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens, turkeys, ducks, and guinea fowls.

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 known cases of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

In case of detection of lack of efficacy during treatment, communicate it to competent national authorities.
This veterinary medicinal product should not be used together with feed additives/or other veterinary medicinal products that might interfere with the efficacy of the product, like ‘coccidiostats’ and ‘histomonostats’.

4.5 Special precautions for use

Special precautions for use in animals

As with any antiparasitic, frequent and repeated use of an anti-protozoal agent of the same class can lead to the development of resistance. If resistance is present it should be considered to use other antiprotozoal from another class/mechanism of action.
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 veterinary 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.
Wear impervious gloves and protective glasses when handling the product.
The selected protective gloves should satisfy the specification 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 package leaflet or label to the physician.
In case of accidental ingestion, rinse the mouth with fresh water, seek medical advice immediately and show the package leaflet or label to the physician.
Those with known hypersensitivity to amprolium or to benzyl alcohol should avoid contact with the product.
Wash hands after use.

Other precautions

Amprolium is 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 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 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 of 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 bodyweight 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, health status, 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:

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

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.

Solubility in drinking water of up to 100 ml product per litre can be used when preparing stock solutions for use in a water proportioner system which subsequently dilutes the product to its correct final concentration. For stock solutions and when using a proportioner, take care not to exceed the maximum solubility. Adjust flow rate settings of the dosing pump according to concentration of the stock solution and water intake of the animals to be treated.

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.

4.11 Withdrawal period(s)

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antiparasitic products, other antiprotozoal agents, 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 coccidia 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.

Environmental properties
Amprolium is a very persistent substance in soil.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
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: 3 months.
Shelf life after dilution according to directions: 24 hours.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and composition of immediate packaging

100 mL bottle: high density polyethylene bottle, closed with a high density polyethylene cap with a tamper evident ring and an expanded polyethylene internal seal.

1L bottle: high density polyethylene bottle, closed with a high density polyethylene cap with an internal seal: low density polyethylene/ PET/ aluminium / paper.

5 L multidose container: high density polyethylene multidose container closed with a high density polyethylene cap with an internal seal: low density polyethylene / PET / aluminium / cardboard.

Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

V.M.D. n.v.
Hoge Mauw 900
2370 Arendonk
Belgium

8. MARKETING AUTHORISATION NUMBER

Vm 19968/4007

9. DATE OF FIRST AUTHORISATION

12 May 2021

10. DATE OF REVISION OF THE TEXT

April 2022

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be supplied only on veterinary prescription.

Approved 12 April 2022