ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE LABEL

{100 mL bottle, 1 L, 5L}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Amprolium: 400.0 mg/ml, equivalent to 452.4 mg of amprolium hydrochloride

3. PHARMACEUTICAL FORM

Solution for use in drinking water.

4. PACKAGE SIZE

100 mL, 1L, 5L

5. TARGET SPECIES

Chickens, turkeys, ducks, and guinea fowls.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
PL: Termin ważności (EXP)
Once diluted use within 24 h.
Shelf life after first opening: 3 months.
Once broached use by …..

11. SPECIAL STORAGE CONDITIONS

Do not store above 30 °C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

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.
UK: POM-V

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

V.M.D. n.v.
Hoge Mauw 900
900 Arendonk
Belgium
Tel.: +32 14 67 20 51
Fax.: +32 14 67 21 52

16. MARKETING AUTHORISATION NUMBER(S)

Vm 19968/4007

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}
PL: Numer serii (Lot)

B. PACKAGE LEAFLET

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

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

Marketing authorisation holder:
V.M.D.n.v.
Hoge Mauw 900, 2370 Arendonk - Belgium

Manufacturer responsible for batch release:
V.M.D.n.v.
Hoge Mauw 900, 2370 Arendonk – Belgium

Or:

Laboratoires Biové
3 Rue de Lorraine, 62510 Arques - France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

SURRICOXX 400 mg/mL Solution for use in drinking water for chickens, turkeys, ducks, and guinea fowls
Amprolium (as hydrochloride)

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

Each ml contains:

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

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

Solution for use in drinking water. Clear yellow solution.

4. INDICATION(S)

In chickens, turkeys, ducks, and guinea fowls:
- Treatment of intestinal coccidiosis caused by *Eimeria* spp. susceptible to amprolium.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

None known.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon. Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Chickens, turkeys, ducks, and guinea fowls.

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

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:

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

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.

Concentrated solutions of up to 100 ml product per litre can be used in a dosing device. The dosing device should then dilute the product to its correct final concentration.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

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

11. 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 label after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 3 months.
Shelf life after dilution according to directions: 24 h.

12. SPECIAL WARNING(S)

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’.

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 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.

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.

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.

Overdose (symptoms, emergency procedures, antidotes):
The adverse effects of amprolium at high doses are caused by thiamine deficiency. Such deficiency can be compensated for by increasing thiamine intake.

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

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

UK: Dispose of any unused medicine or waste materials in accordance with local requirements. Medicines should not be disposed of via wastewater.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

DD/MM/YYYY.

15. OTHER INFORMATION>

Pack sizes: 100 mL bottle, 1L, 5L
Not all pack sizes may be marketed.

Approved 12 May 2021