

**ANNEX I**  
**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 (AT, BE, BG, CZ, DE, EL, ES, HU, IE, IT,LT, LU, LV, MT, NL, PL, PT, RO, SK, UK(NI))  
SURRICOXX (EE)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL contains:

### Active substances:

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

### Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Benzyl alcohol (E1519)	9 mg
Purified water	/

Solution for use in drinking water.  
Clear yellow solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Chickens, turkeys, ducks, and guinea fowls.

### 3.2 Indications for use for each target species

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

### 3.3 Contraindications

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

### 3.4 Special warnings

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'.

### 3.5 Special precautions for use

#### Special precautions for safe use in the target species:

As with any antimicrobial, 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 veterinary medicinal product is not intended for a preventive use. This veterinary medicinal 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 veterinary medicinal product is acidic and may cause irritation to, or corrosion of, the skin, eyes, throat and airways.

Avoid all physical contact with the veterinary medicinal product, including any vapours.

Personal protective equipment consisting of impervious gloves and protective glasses should be worn when handling the veterinary medicinal product.

The selected protective gloves should satisfy the specification of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

In case of contact with skin or eyes, wash immediately the affected area with clean running water, remove any contaminated clothes. If irritation persists, seek medical advice and show the package leaflet or the 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 the label to the physician.

People with known hypersensitivity to amprolium or to benzyl alcohol should avoid contact with the veterinary medicinal product.

Wash hands after use.

Special precautions for the protection of the environment:

Amprolium is a very persistent substance in soil.

### **3.6 Adverse events**

Chickens, turkeys, ducks, and guinea fowls:

Not known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### **3.7 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.

### **3.8 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 simultaneous administration of products containing vitamin B-complex.

### **3.9 Administration routes and dosage**

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 veterinary medicinal product/10 kg bodyweight/day) for 5 to 7 consecutive days.

To ensure a correct dosage, body weight should be determined as accurately as possible

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, clinical condition, breed, and husbandry system. In order to obtain the correct dosage, the concentration of amprolium may need to be adjusted accordingly.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{0.05 \text{ mL of veterinary medicinal product per kg bodyweight per day} \times \text{Average bodyweight (kg) of animals to be treated}}{\text{Average daily water intake (l/animal)}} = \dots \text{ mL of veterinary medicinal product per litre of drinking water}$$

Average daily water intake (l/animal)

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 of the veterinary medicinal 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.

### **3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)**

The adverse effects of amprolium at high doses are caused by thiamine deficiency. Such deficiency can be compensated for by increasing thiamine intake.

### **3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance**

Not applicable.

### **3.12 Withdrawal periods**

Meat and offal: zero days.

Eggs: zero days.

## **4. PHARMACOLOGICAL INFORMATION**

### **4.1 ATCvet code:**

QP51BX02.

### **4.2 Pharmacodynamics**

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.

### **4.3 Pharmacokinetics**

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

Amprolium is excreted mainly via faeces.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

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

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing biocidal products or other substances used in drinking water.

### **5.2 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf life after first opening the immediate packaging: 3 months.

Shelf life after dilution according to directions: 24 hours.

### **5.3 Special precautions for storage**

Do not store above 30 °C.

### **5.4 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.

1 L 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.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

**6. NAME OF THE MARKETING AUTHORISATION HOLDER**

V.M.D. n.v.

**7. MARKETING AUTHORISATION NUMBER(S)**

**8. DATE OF FIRST AUTHORISATION**

Date of first authorisation: {DD/MM/YYYY}.

**9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

{DD/MM/YYYY}

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**100 mL, 1 L, 5 L**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

SURRICOXX 400 mg/mL Solution for use in drinking water for chickens, turkeys, ducks, and guinea fowls (AT, BE, BG, CZ, DE, EL, ES, HU, IE, IT,LT, LU, LV, MT, NL, PL, PT, RO, SK, UK(NI))

**2. STATEMENT OF ACTIVE SUBSTANCES**

Amprolium 400.0 mg/mL  
(Equivalent to 452.4 mg/mL of amprolium hydrochloride)

**3. PACKAGE SIZE**

100 mL

1 L

5 L

**4. TARGET SPECIES**

Chickens, turkeys, ducks, and guinea fowls.

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

In drinking water use

**7. WITHDRAWAL PERIODS**

Withdrawal periods:

Meat and offal: zero days.

Eggs: zero days.

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened, use within 3 months.

Once diluted, use within 24 hours.

**9. SPECIAL STORAGE PRECAUTIONS**

Do not store above 30 °C.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

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

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

V.M.D. n.v.

**14. MARKETING AUTHORISATION NUMBERS**

EU/0/00/000/000

**15. BATCH NUMBER**

Lot {number}

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

SURRICOXX 400 mg/mL Solution for use in drinking water for chickens, turkeys, ducks, and guinea fowls (AT, BE, BG, CZ, DE, EL, ES, HU, IE, IT,LT, LU, LV, MT, NL, PL, PT, RO, SK, UK(NI))

### 2. Composition

Each mL contains:

#### Active substances:

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.

### 3. Target species

Chickens, turkeys, ducks, and guinea fowls.

### 4. Indications for use

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

### 5. Contraindications

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

### 6. Special warnings

#### Special warnings:

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 safe use in the target species:

As with any antimicrobial, 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 veterinary medicinal product is not intended for a preventive use. This veterinary medicinal 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 veterinary medicinal product is acidic and may cause irritation to, or corrosion of, the skin, eyes, throat and airways.

Avoid all physical contact with the veterinary medicinal product, including any vapours.

Personal protective equipment consisting of impervious gloves and protective glasses should be worn when handling the veterinary medicinal product.

The selected protective gloves should satisfy the specification of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

In case of contact with skin or eyes, wash immediately the affected area with clean running water, remove any contaminated clothes. If irritation persists, seek medical advice and show the package leaflet or the 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 the label to the physician.

People with known hypersensitivity to amprolium or to benzyl alcohol should avoid contact with the veterinary medicinal product.

Wash hands after use.

Special precautions for the protection of the environment:

Amprolium is a very persistent substance in soil.

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 simultaneous administration of products containing vitamin B-complex.

Overdose:

The adverse effects of amprolium at high doses are caused by thiamine deficiency. Such deficiency can be compensated for by increasing thiamine intake.

Major incompatibilities:

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

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing biocidal products or other substances used in drinking water.

## **7. Adverse events**

Chickens, turkeys, ducks, and guinea fowls:

Not known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

## **8. Dosage for each species, routes 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 veterinary medicinal product/10 kg bodyweight/day) for 5 to 7 consecutive days.

To ensure a correct dosage, body weight should be determined as accurately as possible. 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, clinical condition, breed, and husbandry system. In order to obtain the correct dosage, the concentration of amprolium may need to be adjusted accordingly.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{0.05 \text{ mL of veterinary medicinal product per kg bodyweight per day} \times \text{Average bodyweight (kg) of animals to be treated}}{\text{Average daily water intake (l/animal)}} = \dots \text{ mL of veterinary medicinal product per litre of drinking water}$$

Average daily water intake (l/animal)

## **9. Advice on correct administration**

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 of the veterinary medicinal 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.

## **10. Withdrawal periods**

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 immediate packaging: 3 months.

Shelf life after dilution according to directions: 24 hours.

## **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## **14. Marketing authorisation numbers and pack sizes**

XXX

100 mL bottle.

1 L bottle.

5 L container.

Not all pack sizes may be marketed.

## **15. Date on which the package leaflet was last revised**

{DD/MM/YYYY}

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

## **16. Contact details**

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

Local representatives and contact details to report suspected adverse events:

**België/Belgique/Belgien**

{Nom/Naam/Name}  
{Adresse/Adres/Anschrift}  
BE-0000 {Localité/Stad/Stadt}  
Tél/Tel: + {N° de téléphone/Telefoonnummer/  
Telefonnummer}  
<{E-mail}>

**Република България**

{Наименование}  
{Адрес}  
BG {Град} {Пощенски код}  
Тел: + {Телефонен номер}  
<{E-mail}>

**Česká republika**

{Název}  
{Adresa}  
CZ {město}  
Tel: +{telefonní číslo}  
<{E-mail}>

**Danmark**

{Navn}  
{Adresse}  
DK-0000 {by}  
Tlf.: + {Telefonnummer}  
<{E-mail}>

**Deutschland**

{Name}  
{Anschrift}  
DE-00000 {Stadt}  
Tel: + {Telefonnummer}  
<{E-mail}>

**Eesti**

(Nimi)  
(Address)  
EE - (Postiindeks) (Linn)  
Tel: +(Telefoninumber)  
<{E-mail}>

**Ελλάδα**

{Όνομα}  
{Διεύθυνση}  
EL-000 00 {πόλη}  
Τηλ: + {Αριθμός τηλεφώνου}  
<{E-mail}>

**Lietuva**

{pavadinimas}  
{adresas}  
LT {pašto indeksas} {miestas}  
Tel: + {telefono numeris}  
<{E-mail}>

**Luxembourg/Luxemburg**

{Nom}  
{Adresse}  
L-0000 {Localité/Stadt}  
Tél/Tel: + {N° de téléphone/Telefonnummer}  
<{E-mail}>

**Magyarország**

{Név}  
{Cím}  
HU-0000 {Város}  
Tel.: + {Telefonszám}  
<{E-mail}>

**Malta**

{Isem}  
{Indirizz}  
MT-0000 {Belt/Raħal}  
Tel: + {Numru tat-telefon}  
<{E-mail}>

**Nederland**

{Naam}  
{Adres}  
NL-0000 XX {stad}  
Tel: + {Telefoonnummer}  
<{E-mail}>

**Norge**

{Navn}  
{Adresse}  
N-0000 {poststed}  
Tlf: + {Telefonnummer}  
<{E-mail}>

**Österreich**

{Name}  
{Anschrift}  
A-00000 {Stadt}  
Tel: + {Telefonnummer}  
<{E-mail}>

**España**

{Nombre}  
{Dirección}  
ES-00000 {Ciudad}  
Tel: + {Teléfono}  
<{E-mail}>

**France**

{Nom}  
{Adresse}  
FR-00000 {Localité}  
Tél: + {Numéro de téléphone}  
<{E-mail}>

**Hrvatska**

{Ime}  
{Adresa}  
{Poštanski broj} {grad}  
Tel: + {Telefonski broj}  
<{e-mail}>

**Ireland**

{Name}  
{Address}  
{Town} {Postal code} - IE  
Tel: + {Telephone number}  
<{E-mail}>

**Ísland**

{Nafn}  
{Heimilisfang}  
IS-000 {Borg/Bær}  
Sími: + {Símanúmer}  
<{Netfang}>

**Italia**

{Nome}  
{Indirizzo}  
IT-00000 {Località}  
Tel: + {Numero di telefono}  
<{E-mail}>

**Κύπρος**

{Όνομα}  
{Διεύθυνση}  
CY-000 00 {πόλη}  
Τηλ: + {Αριθμός τηλεφώνου}  
<{E-mail}>

**Latvija**

{Nosaukums}  
{Adrese}  
{Pilsēta}, LV {Pasta indekss }  
Tel: + {Telefona numurs}  
<{E-mail}>

**Polska**

{Nazwa/ Nazwisko:}  
{Adres:}  
PL – 00 000 {Miasto:}  
Tel.: + {Numer telefonu:}  
<{E-mail}>

**Portugal**

{Nome}  
{Morada}  
PT-0000–000 {Cidade}  
Tel: + {Número de telefone}  
<{E-mail}>

**România**

{Nume}  
{Adresă}  
{Oraș} {Cod poștal} – RO  
Tel: + {Număr de telefon}  
<{E-mail}>

**Slovenija**

{Ime}  
{Naslov}  
SI-0000 {Mesto}  
Tel: + {telefonska številka}  
<{E-mail}>

**Slovenská republika**

{Meno}  
{Adresa}  
SK-000 00 {Mesto}  
Tel: + {Telefónne číslo}  
<{E-mail}>

**Suomi/Finland**

{Nimi/Namn}  
{Osoite/Adress}  
FI-00000 {Postitoimipaikka/Stad}  
Puh/Tel: + {Puhelinnumero/Telefonnummer}  
<{E-mail}>

**Sverige**

{Namn}  
{Adress}  
SE-000 00 {Stad}  
Tel: + {Telefonnummer}  
<{E-mail}>

**United Kingdom (Northern Ireland)**

{Name}  
{Address}  
{Town} {Postal code} – UK  
Tel: + {Telephone number}  
<{E-mail}>>

**<17. Other information>**