

## **SUMMARY OF PRODUCTS CHARACTERISTICS**

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

Copinox Lamb 2 g Capsule, Hard

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

#### Active Substance

Each 2g capsule provides copper oxide equivalent to 1.74g elemental copper

#### Excipients

E171 – Titanium dioxide 1.9 % w/w

For full list of excipients see Section 6.1

### **3. PHARMACEUTICAL FORM**

Capsule, hard.  
White capsule size Oel

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Sheep, (lambs)

#### **4.2 Indications for use, specifying the target species**

For the prevention and treatment of hypocuprosis in sheep

#### **4.3 Contra-indications**

Do not use unless copper deficiency is known to exist or known to be a risk.  
Do not administer to pre-ruminant lambs or lambs under 10kg bodyweight or less than 5 weeks old.

#### **4.4 Special warnings for each target species**

Caution is advised and veterinary advice should be sought before treating housed sheep and breeds such as North Ronaldsays, Texels and Lleyns known to be sensitive to copper poisoning.

This product is not effective in alleviating signs of swayback in lambs which already show signs of the disease.

#### **4.5 Special precautions for use**

- i. Special precautions for use in animals  
Animals should only be dosed if copper deficiency is known to exist or known to be a risk.

No other form of copper supplementation should be given immediately prior to or 6 months after administration of the capsules.

Do not exceed the recommended dose.

Care must be taken when dosing animals to avoid causing injury to the mouth and pharynx.

- ii. Special precautions for the person administering the veterinary medicinal product to animals  
None.
- iii. Other precautions  
None.

#### **4.6 Adverse reactions (frequency and seriousness)**

Not to be expected provided the recommended dosage regimes are followed.

#### **4.7 Use during pregnancy, lactation or lay**

No adverse effects known

#### **4.8 Interaction with other medicinal products and other forms of interaction**

Copper reacts with many elements, the most important of which is molybdenum. This interaction may lead to the formation of insoluble copper molybdates which may reduce absorption of copper from the gut.

#### **4.9 Amount(s) to be administered and administration route**

For oral administration.

Lambs (over 10kg bodyweight and over 5 weeks old) receive one 2g (white) capsule (equivalent to 200mg CuO/Kg for a 10kg lamb).

The capsules should be administered orally over the back of the tongue by use of a dosing gun/standard drench gun fitted with the special adaptors provided. The capsule is inserted at one end and the other end attached to the drench gun. The capsule is ejected by expulsion with water. Always check the animal swallows the capsule.

To be used at intervals of not less than 6 months.

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

Copper toxicity may lead to the following clinical signs; thirst, apathy, haemolytic crises, jaundice, hepatic necrosis and death.  
No specific antidote is available for use in food producing animals.

**4.11 Withdrawal period(s)**

Meat – zero days  
Milk – zero hours

**5. PHARMACOLOGICAL PROPERTIES**

**Pharmacotherapeutic group:** Mineral supplements, other.

**ATC Vet Code:** QA12CX

**5.1 Pharmacodynamic properties**

The effect is to provide a supplementary source of a single nutrient, copper, over a prolonged period of time. Copper oxide rods are released in the reticulo-rumen, passing slowly through the ruminant stomachs for a period of 2 to 3 months. Exposure to abomasal acidity causes slow particle solution, enabling partial absorption to take place.

**5.2 Pharmacokinetic properties**

The copper stored in the liver then acts as a depot from which copper is slowly released to maintain normal concentrations in the blood during periods when the animal may be receiving an inadequate copper intake.

The recommended dosage should maintain adequate copper levels for the whole grazing season unless more frequent dosing is required on veterinary advice.

**5.3 Environmental properties**

Not applicable

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Titanium Dioxide (E171 - capsule colourant)  
Hypromellose

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 4 years

### **6.4 Special precautions for storage**

Do not store above 25°C.  
Protect from light.  
Protect from frost.  
Protect from moisture  
Store in a dry place.  
Partly used containers should be closed

### **6.5 Nature and composition of immediate packaging**

100 or 250 capsules contained within a white opaque polypropylene tub with a paper/foam spacer or foam spacer sealed with a white opaque polypropylene screw fit lid.

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, 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**

Animax Ltd  
Shepherds Grove West  
Stanton  
Bury St Edmunds  
Suffolk  
IP31 2AR

**8. MARKETING AUTHORISATION NUMBER**

Vm 14016/4002

**9. DATE OF FIRST AUTHORISATION**

23 December 1999

**10. DATE OF REVISION OF THE TEXT**

July 2022

Approved 22 July 2022

A handwritten signature in black ink, consisting of a stylized, cursive 'H' followed by the name 'Hunter.' with a period at the end.