

## **SUMMARY OF PRODUCTS CHARACTERISTICS**

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

Copasure 24g capsule, hard.

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

Each capsule contains

#### **Active Substance**

Copper Oxide	24.00 g
(equivalent to elemental copper)	20.88 g)

#### **Excipients**

Capsule	
Sunset Yellow (E110)	0.0016 g
Erythrosine (E127)	0.0080 g
Titanium dioxide (E171)	0.0066 g
Iron oxide (E172)	0.0042 g
Methyl Parahydroxybenzoate	0.0068 g
Propyl Parahydroxybenzoate	0.0017 g

For a full list of excipients see Section 6.1.

### **3. PHARMACEUTICAL FORM**

Capsule, hard.

Maroon capsule of approximately 48mm length and 20mm diameter, (Size 11L).

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Cattle.

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

For the prevention and treatment of hypocuprosis in cattle.

#### **4.3 Contraindications**

Do not use unless copper deficiency is known to exist or known to be a risk.  
Do not administer to pre-ruminant animals.

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

Do not administer to calves under 100kg or pre-ruminant calves.

#### **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 required.
- 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.

Young stock (100-300kg bw) receive one 24g (maroon) capsule, (equivalent to 80 mg copper oxide/kg for a 300 kg animal).

Cattle (over 300kg bw) receive one or two 24g (maroon) capsules, depending on the severity of the copper deficiency (one capsule is equivalent to 60 mg copper oxide/kg for a 400 kg animal, two capsules are equivalent to 120 mg copper oxide/kg for a 400 kg animal).

The capsules should be administered orally over the back of the tongue. Cattle are dosed using conventional balling guns, follow the instructions supplied with the balling gun. Always check the animal has swallowed the capsule.

To be used at intervals of not less than 6 months. The recommended dosage should maintain adequate copper levels for the whole grazing season unless more frequent dosing is recommended on veterinary advice.

#### **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.

**ATCVet 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**

Capsule  
E110 - Sunset Yellow  
E127 - Erythrosine  
E171 - Titanium Dioxide  
E172 - Iron Oxide  
Methyl parahydroxybenzoate  
Propyl parahydroxybenzoate  
Sodium lauryl sulfate  
Porcine gelatine

### **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 freezing.  
Protect from moisture. Store in a dry place.  
Partly used containers should be tightly closed.

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

24 capsules contained in a cardboard trays with perforated supports, in an outer cardboard box, sealed with a polyethylene coating

### **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 14016/4003

**9. DATE OF FIRST AUTHORISATION**

24 May 2002

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

July 2023

Approved 4 July 2023

A handwritten signature in black ink, appearing to read "Hunter.", is written below the approval date. The signature is stylized and cursive.