

SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Copinox Cattle 24g capsule, hard.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains

Active Substance

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

Excipients

Capsule shell	
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.

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.

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

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 frost.
Protect from moisture.
Store in a dry place.
Partly used containers should be closed.

6.5 Nature and composition of immediate packaging

24 capsules contained in a shrink wrapped polyethylene coated cardboard tray with perforated supports sealed with a polyethylene coated cardboard lid.

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
U.K.

8. MARKETING AUTHORISATION NUMBER(S)

Vm14016/4000.

9. DATE OF FIRST AUTHORISATION

Date: 23rd December 1999.

10. DATE OF REVISION OF THE TEXT

Date: July 2010