

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Copasure 27g Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 27g capsule contains:

Active Substance

Copper oxide	27.0 g
(equivalent to elemental copper	23.5 g)

Excipients

Gelatin capsule

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Capsule, hard.

Maroon coloured hard gelatin capsules containing copper particles of needle-form shape.

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 administer to pre-ruminant animals.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

Animals should be only 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 for 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Copper oxide can cause irritation to skin, eyes and respiratory tract. However, the user is protected from the copper oxide by the gelatin capsule. In the event of a capsule being broken, the copper oxide particles can be disposed of with domestic waste, and hands should be washed.

No special handling is required and no protective clothing is required.

If the user does get copper oxide in his eyes he should rinse them thoroughly
If the user does get copper oxide in his mouth he should rinse his mouth, taking care not to swallow. If the user does ingest copper oxide he should drink a large glass of water and seek medical attention.

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 interactions

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 Amounts to be administered and administration route

Young stock (100-250 kg bw) receive one 27g (maroon) capsule (equivalent to 108 mg CuO/kg for a 250 kg animal).
Cattle (over 250 kg bw) receive one or two 27g (maroon) capsules, depending on the severity of the copper deficiency (One capsule is equivalent to 67.5 mg CuO/kg for a 400 kg animal, 2 capsules are equivalent to 135 mg CuO/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. Always check the animal has swallowed the capsule.

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

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

Haemoglobinuria, jaundice - no special antidote (Symptomatic treatment, blood transfusion, etc).

4.11 Withdrawal period(s)

Meat and milk - nil.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Alimentary tract and metabolism ATC vet code: QA12C

5.1 Pharmacodynamic properties

Active substance: Copper oxide particles

The effect is to provide a supplementary source of a single nutrient, copper, over a prolonged period of time.

5.2 Pharmacokinetic particulars

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. 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Porcine Gelatin
Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Sodium Lauryl Sulphate
Sunset Yellow (E110)
Erythrosine (E127)
Titanium Dioxide (E171)
Iron Oxide (E172)

6.2 Major 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 direct sunlight.
Protect from frost.
Keep the tub tightly closed in order to protect from moisture.

6.5 Nature and composition of immediate packaging

Rectangular trays made from cardboard with perforated supports, containing 24 x 27 g maroon gelatin capsules filled with copper oxide particles. Trays have strong lids and are individually shrink-wrapped.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

VPA23127/001/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29 June 2001

Date of last renewal: 28 June 2006

10 DATE OF REVISION OF THE TEXT

October 2021