Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Copasure 4g Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4g capsule contains:

Active Substance

Copper oxide	4.00g
(equivalent to elemental copper	3.5 g)

Excipient
Gelatin capsule

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Capsule, hard.
White coloured hard gelatin capsules containing copper particles of needle-form shape.

4 CLINICAL PARTICULARS

4.1 Target Species

Ewes, calves.

4.2 Indications for use, specifying the target species

For the prevention and treatment of hypocuprosis in sheep and cattle.

4.3 Contraindications

Do not use in pre-ruminant calves, in calves under 75 kg bodyweight or less than 2 months of age.

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 Lleyn known to be sensitive to copper poisoning.

4.5 Special precautions for use

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.

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

Adult sheep (50kg) receive one 4g (white) capsule (equivalent to 80 mg CuO / kg for a 50 kg sheep).
Calves (Ruminant calves 75-100 kg and over 2 months of age) receive two 4g (white) capsules (equivalent to 80 mg CuO/kg for a 100 kg calf).

Adult sheep and calves may be dosed with standard drench guns fitted with the special adapter provided. The 4g capsule is inserted at one end and the other is attached to the drenching gun. The capsule is expelled by expulsion with water. Conventional balling guns may also be employed. Always check the animal has swallowed the capsule.

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

In ewes, for the prevention of congenital swayback, the dose should be given during the second or third month of gestation.

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 needles
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

Capsule
Gelatin
Titanium Dioxide (E171)

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

Cylindrical tubs of food quality white polypropylene, with screw fitting airtight closures. Within the tub 5 mm polyol foam spacers top and bottom protect 100 x 4 g white gelatin capsules filled with copper oxide particles.

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

Carr's Supplements (ROI) Ltd, Dublin
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8 MARKETING AUTHORISATION NUMBER(S)

VPA23127/001/002

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