SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Copinox Ewe/Calf 4 g Capsule, Hard

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance
Each 4g capsule provides copper oxide
equivalent to 3.48g elemental copper

Excipients
E171 - Titanium dioxide 1.9% w/w

For a full list of excipients see Section 6.1

3. PHARMACEUTICAL FORM

Capsule, hard.
Size 000 white coloured capsule

4. CLINICAL PARTICULARS

4.1 Target species

Sheep, Cattle (calves)

4.2 Indications for use, specifying the target species

For the prevention and treatment of hypocuprosis in cattle and sheep

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

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.

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

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 only.

Adult sheep (50kg) receive one 4g (ivory) capsule (equivalent to 80 mg CuO/kg for a 50 kg sheep).

Calves (ruminant calves 75-100kg and over 2 months of age) receive two 4g (ivory) 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 adapters provided. The 4g capsule is inserted at one end and the other is attached to the drench gun. The capsule is ejected 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 at tupping or during the first half of pregnancy. It may be advisable to administer the dose during the second or third month of gestation rather than at tupping on farms where copper deficiency is particularly severe.

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

Copper toxicity may lead to the following clinical signs; thirst, apathy, haemolytic anaemia, 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

Hypromellose
E171 titanium dioxide

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged: 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

50, 100 or 250 capsules contained within a white opaque polypropylene tub with a paper/foam spacer or foam spacer sealed with a white paque 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 14016/4001

9. DATE OF FIRST AUTHORISATION

23 December 1999

10. DATE OF REVISION OF THE TEXT

July 2022

Approved 22 July 2022