

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. {NATURE/TYPE}

[The guidance contained below is national specific only and should be used in addition to EU QRD template guidance for both the Package Leaflet AND the Outer/Immediate package, available on the EMA website.]

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Animax Limited

Shepherds Grove West

Stanton

Bury St Edmunds

Suffolk

IP31 2AR

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Copinox Ewe/Calf 4g Capsule, Hard.

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Each capsule contains 4g copper oxide rods equivalent to 3.48g copper.

4. PHARMACEUTICAL FORM

Hard capsule for oral administration

5. PACKAGE SIZE

250 (100 or 50) capsules

6. INDICATION(S)

For the treatment and prevention of copper deficiency in ewes and calves and for the prevention of congenital swayback in lambs.

7. CONTRAINDICATIONS

Do not use in house sheep or breeds of sheep known to be particularly susceptible to copper toxicity such as North Ronaldsay, Texel and Lleyn. Do not use in lambs or pre-ruminant calves, in calves under 75 kg bodyweight or less than 2 months of age. Do not exceed the recommended dose. No other form of copper supplementation should be given immediately prior to or for six months after the administration of Copinox capsules.

8. ADVERSE REACTIONS

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.

9. TARGET SPECIES

Ewes and calves.

10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral administration only. The copper status of the flock or herd should be known prior to use. If in doubt consult your veterinary surgeon. To be used at intervals of not less than 6 months.

Ewes - One 4g capsule per ewe. 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.

Ruminant calves - 75 – 100Kg bodyweight may be given two 4g capsules.

11. ADVICE ON CORRECT ADMINISTRATION

Care should be taken when dosing animals to avoid injury to the mouth and pharynx. Copinox capsules may be administered with a suitable balling gun taking care to avoid choking and throat damage. Alternatively the supplied capsule holder may be fitted to the end of a conventional liquid drenching gun. Capsules placed in the holder may be expelled by e.g., water (about 5 ml is adequate). This helps to stimulate swallowing. Always check the animal swallows the capsule.

12. WITHDRAWAL PERIOD

Meat – zero days; Milk – zero hours

13. SPECIAL STORAGE PRECAUTIONS

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.

14. SPECIAL WARNING(S)<User Warnings>

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. If signs of disease persist or appear consult your veterinary surgeon.

15. EXPIRY DATE

As packaged 4 years

16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Rinse containers thoroughly with water. Dispose of rinsings in slurry or dirty water. Dispose of rinsed container in the farm refuse. Used containers should not be recycled.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

July 2022

Find more product information by searching for the Product Information Database 'PID' on www.gov.uk.

18. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal Treatment Only

AVM-GSL

19. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children

20. MARKETING AUTHORISATION NUMBER(S)

Vm 14016/4001

21. MANUFACTURER’S BATCH NUMBER

BN:

Approved 22 July 2022

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