

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® 24g Capsule, hard

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

Each capsule contains 24g copper oxide rods equivalent to 20.88g copper.

4. PHARMACEUTICAL FORM

Hard gelatine capsule for oral administration

5. PACKAGE SIZE

24 capsules

6. INDICATION(S)

For the treatment and prevention of copper deficiency in cattle over 100kg.

7. CONTRAINDICATIONS

Do not use in pre-ruminant cattle or in cattle weighing less than 100kg. Do not exceed the recommended dose. Do not use unless 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 six months after the administration of Copinox® capsules.

Ruminating calves weighing 75 – 100 kg may be administered 2 x 4 g capsules of the alternative Copinox product.

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

Cattle.

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

For oral administration only. The copper status of the 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.

Young cattle – 100 to 300kg One 24g capsule.

Adult cattle - over 300kg, 1 or 2 24g capsule(s) depending on the severity of deficiency.

Ruminating Calves – 75 – 100 kg, may be given 2 x 4 g capsules of Copinox Ewe/Calf 4 g. **11. ADVICE ON CORRECT ADMINISTRATION**

The capsules should be administered orally over the back of the tongue. 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. Follow instructions supplied with the balling gun. Always check the animal swallows the capsule.

The copper oxide rods are retained for two or three months in the ruminant digestive tract, slowly releasing copper and elevating liver stores for approximately six months. Use of Copinox® is appropriate in both primary and secondary copper deficiency.

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.
Replace lid on partly used pack.
Partly used containers should be closed.

14. SPECIAL WARNING(S)<User Warnings>

Inadequate copper levels may be due to insufficient copper in the diet (primary copper deficiency). Secondary copper deficiency results from the adverse effects of molybdenum, iron or sulphur on copper absorption. If signs of disease persist or appear consult your veterinary surgeon.

15. EXPIRY DATE

Exp:

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

Dispose of empty packaging and any unused capsules in the farm refuse.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

April 2017

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 reach of children

20. MARKETING AUTHORISATION NUMBER(S)

Vm 14016/4000

21. MANUFACTURER'S BATCH NUMBER

BN:

Approved: 26/04/2017

