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

Marketing Authorisation Holder:
Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

Manufacturer responsible for batch release:
Lelypharma BV
Zuiveringsweg 42
8243 PZ
Lelystad
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxycare Tablets 250mg

3. STATEMENT OF THE ACTIVE INGREDIENT

Each film-coated tablet contains:

An active ingredient:
Oxytetracycline dihydrate 250mg.

4. PHARMACEUTICAL FORM

Yellow round convex tablets with a cross-snap-tab on one side to allow quarter split.

5. PACKAGE SIZE

1000 tablets

6. INDICATION

Use: For the treatment of oxytetracycline sensitive based bacterial disease.

7. CONTRAINDICATIONS

Contraindications/warnings: Contraindicated in patients with hypersensitivity to any tetracyclines. Do not administer concurrently with milk or antacids

Oxytetracycline is deposited in growing teeth and bones and may cause yellow discolouration.

It also crosses the placenta. For this reason it is not recommended in late pregnancy or in young animals.

Caution must be taken in treating animals with renal or hepatic dysfunction, in such cases it may be necessary to reduce dosage levels.

If you know you are hypersensitive (allergic) to oxytetracycline, do not handle the product. In the event of accidental ingestion, flush mouth with plenty of water and seek medical advice. In the event of eye contact, flush thoroughly with clean, running water. If irritation persists seek medical attention. Wash hands after use.

8. ADVERSE REACTION(S)

9. TARGET SPECIES

Dogs.

10. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage and administration: In dogs: Initial dose of 50mg/kg body weight followed by 25mg/kg every 12 hours for 5 days. For oral administration at least one hour before or two hours after feeding.

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

13. SPECIAL STORAGE PRECAUTIONS

Do not store above 25^{o}C. Return any ¼ tablet to the pot and use within 48 hours. Protect from light.

14. SPECIAL WARNINGS

User Warnings

15. EXPIRY DATE

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

Disposal advice: Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

August 2022

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

POM-V

For animal treatment only. To be supplied only on veterinary prescription.

19. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

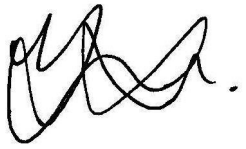
Keep out of sight and reach of children.

20. MARKETING AUTHORISATION NUMBER

Vm 32742/4032

21. MANUFACTURER'S BATCH NUMBER

22. OTHER INFORMATION



Approved: 11 August 2022