ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrocare 25 mg/ml concentrate for oral solution for pet rabbits, rodents, ornamental birds and reptiles.
Enrofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: Enrofloxacin 25mg

3. PHARMACEUTICAL FORM

Concentrate for Oral Solution

4. PACKAGE SIZE

20ml
100ml

5. TARGET SPECIES

Pet rabbits, rodents, ornamental birds and reptiles.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Do not use in animals producing food intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once broached use within 90 days

Once diluted any medicated liquid remaining 24 hours after preparation must be discarded.

11. SPECIAL STORAGE CONDITIONS

Keep the bottle in the outer carton.

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

Disposal: read package leaflet.

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

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

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 32742/4031

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrocare 25 mg/ml concentrate for oral solution for pet rabbits, rodents, ornamental birds and reptiles.
Enrofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: Enrofloxacin 25mg

3. PHARMACEUTICAL FORM

Concentrate for Oral Solution

4. PACKAGE SIZE

20ml
100ml

5. TARGET SPECIES

Pet rabbits, rodents, ornamental birds and reptiles.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Do not use in animals producing food intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once broached use within 90 days

Once diluted any medicated liquid remaining 24 hours after preparation must be discarded.

11. SPECIAL STORAGE CONDITIONS

Keep the bottle in the outer carton.

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

Disposal: read package leaflet.

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

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

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 32742/4031

17. MANUFACTURER'S BATCH NUMBER

Lot:

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Enrocare 25 mg/ml concentrate for oral solution for pet rabbits, rodents, ornamental birds and reptiles.

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:
Laboratorios Karizoo, S.A.
c/ Mas Pujades 11-12
Polígono Industrial La Borda
Caldes de Montbui
08140
Barcelona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrocare 25 mg/ml concentrate for oral solution for pet rabbits, rodents, ornamental birds and reptiles.
Enrofloxacin

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

Each ml contains:

Enrofloxacin 25 mg

Benzyl Alcohol as a preservative 14.0 mg

Clear solution
Concentrate for oral solution

4. INDICATION(S)

Pet rabbits
Treatment of infections of the digestive and respiratory tracts caused by enrofloxacin susceptible strains of: *Escherichia coli, Pasteurella multocida and Staphylococcus spp*.

Treatment of skin and wound infections caused by enrofloxacin susceptible strains of *Staphylococcus aureus*.

Rodents, reptiles and ornamental birds
Treatment of infections of the digestive and respiratory tracts where clinical experience, if possible, supported by susceptibility testing of the causal organism, indicates enrofloxacin as the substance of choice.

5. CONTRAINDICATIONS

The product should not be used for prophylaxis.

Do not use in cases of confirmed or suspected resistance to quinolones, since a high degree or cross resistance between enrofloxacin and other quinolones exists.

Do not use in cases of hypersensitivity to fluoroquinolones or to any of the excipients.

Do not use in animals that are epileptic or suffer from seizures since enrofloxacin may cause CNS stimulation.

6. ADVERSE REACTIONS

During the period of rapid growth, enrofloxacin may affect articular cartilage.
If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Pet rabbits, rodents, ornamental birds and reptiles.

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

For administration by gavage or in drinking water.

Dosage
Owing to physiological and pharmacokinetic differences between the wide range of species for which this product is indicated, the dose rates below are for guidance only. Depending upon the species of animal and the infection to be treated, alternative doses may be appropriate using an evidence-based approach. However, any change in dosing regimen should be based on a benefit:risk assessment by the responsible veterinarian, as tolerance at higher doses has not been investigated.

Pet rabbits and rodents: 5 mg enrofloxacin per kg bodyweight (0.2 ml per kg bodyweight) orally diluted in water, twice daily for 7 days.

Reptiles: 5 mg enrofloxacin per kg bodyweight (0.2 ml per kg bodyweight) orally diluted in water, at 24-48 hour intervals for 6 days.

Reptiles are ectothermic, relying on external heat sources to maintain their body temperature at the optimum level for correct function of all body systems. Metabolism

of substances and activity of the immune system are, thus, critically dependant on the body temperature. Therefore, the veterinarian must be aware of correct temperature requirements of the respective reptile species and the hydration status of the individual patient. Furthermore, it has to be considered that large differences exist in the pharmacokinetic behaviour of enrofloxacin among different species, which additionally will influence the decision about the correct dosage of the veterinary medicinal product. Therefore, the recommendations made here can only be used as a starting point for individual dose setting.

Ornamental birds: 10 mg enrofloxacin per kg bodyweight (0.4 ml per kg bodyweight), orally diluted in water, twice daily for 7 days.

9. ADVICE ON CORRECT ADMINISTRATION

The undiluted veterinary medicinal product is strongly alkaline and, therefore, to avoid caustic effects, it is essential to dilute the product with at least 4 parts water prior to administration. In the case of smaller animals (weighing less than 500 g), it may be appropriate to dilute 0.1 ml of the neat product with >4 parts water and administer a proportion of the total volume.

If the product is to be given via the drinking water, concentrations of between 50 and 200 ppm should be considered as suitable working dilutions; concentrations in excess of 250 ppm should be avoided as precipitation may occur.

Medicated fluids should be made up immediately prior to provision on a daily basis.

20 ml bottle: A 3 ml syringe is provided with the 20 ml bottle for withdrawal of the product and facilitation of dilution prior to administration. This syringe has graduations of 0.1 ml. It is recommended to draw up a minimum of 0.1 ml of product prior to dilution since it is not possible to accurately measure volumes that are lower than this.

100 ml bottle: A 10 ml syringe is provided with the 100 ml bottle for withdrawal of the product and facilitation of dilution prior to administration. This syringe has graduations of 0.2 ml. It is recommended to draw up a minimum of 0.2 ml of product prior to dilution since it is not possible to accurately measure volumes that are lower than this.

To withdraw product, firmly insert the syringe hub into the centre of the self-sealing syringe adaptor of the bottle and remove the required amount.

To avoid inhalation of the medication, care should be taken with restraint of the animal and administration of the product.

10. WITHDRAWAL PERIOD

Do not use in animals producing food intended for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Keep the bottle in the outer carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton. The expiry date refers to the last day of the month.

Shelf life after first opening the container: 90 days
Shelf life after dilution: Any medicated liquid remaining 24 hours after preparation must be discarded.

12. SPECIAL WARNING(S)

Special warnings for each target species:
None.

Special precautions for use in animals:

Official and local antimicrobial policies should be taken into account when the product is used.
Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials.

Whenever possible, fluoroquinolones should only be used based on susceptibility testing.

Use of the product deviating from the instructions given in the package leaflet may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.

Special caution should be taken when using enrofloxacin in animals with impaired renal function.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

This product may cause allergic reactions in those that are sensitive. People with known hypersensitivity to (fluoro)quinolones or to any of the excipients should avoid contact with the product.
The undiluted product is strongly alkaline and may cause irritation if it comes into contact with the skin or eyes.
Avoid skin and eye contact.
Wear impermeable gloves when administering the product.
Rinse any splashes from skin or eyes immediately with water.
If irritation persists, seek medical advice.
Wash hands and exposed skin after use.
Do not smoke, eat or drink when handling the product.

Use during Pregnancy, Lactation or lay:

The safety of the veterinary medicinal product has not been established during pregnancy, lactation or lay. Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Do not use enrofloxacin concomitantly with antimicrobial substances acting antagonistically to quinolones (e.g. macrolides, tetracyclines or phenicols). The simultaneous application of substances containing aluminium, calcium or magnesium can impair the absorption of enrofloxacin.

Overdose (symptoms, emergency procedures, antidotes):

In cases of accidental overdose, digestive tract disorders (e.g. vomiting, diarrhoea) and neurological disorders may occur. There is no antidote and treatment should be symptomatic.

Incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

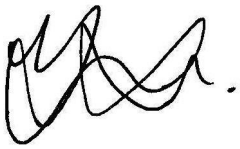
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2022

15. OTHER INFORMATION>

Pack sizes: 20ml and 100ml
Not all pack sizes may be marketed.

To be supplied only on a veterinary prescription



Approved: 11 August 2022