ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrobactin Exoflox vet. 25 mg/ml concentrate for oral solution for pet rabbits, rodents, ornamental birds and reptiles
enrofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:
Active substance:

Enrofloxacin 25 mg

3. PHARMACEUTICAL FORM

Concentrate for oral solution

4. PACKAGE SIZE

10 ml
30 ml
50 ml

5. TARGET SPECIES

Pet rabbits, rodents, ornamental birds and reptiles

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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.
Do not administer undiluted product.

10. EXPIRY DATE

EXP
Shelf life after first opening the immediate packaging: 28 days
Once opened use by _____
Shelf life after dilution according to directions: use immediately

11. SPECIAL STORAGE CONDITIONS

Keep the bottle tightly closed.

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

Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 41821/4026

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle (10 ml, 30 ml and 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrobactin Exoflox vet. 25 mg/ml concentrate for oral solution for pet rabbits, rodents, ornamental birds and reptiles
enrofloxacin

2. QUANTITY OF THE ACTIVE SUBSTANCE

Enrofloxacin 25 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml
30 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

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

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP
Shelf life after first opening the immediate packaging: 28 days.
Shelf life after dilution according to directions: use immediately.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Enrobactin Exoflox vet. 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:
Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

Manufacturer responsible for batch release:
Floris Veterinaire Produkten B.V.
Kempenlandstraat 33
5262 GK Vught
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrobactin Exoflox vet. 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)

Contains per ml:
Active substance:
Enrofloxacin 25 mg

Excipient(s)
Benzyl alcohol (E-1519) 18 mg

Description:
Clear slightly yellow solution.

4. INDICATIONS

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

Do not use in cases of known hypersensitivity to the active substance, to other (fluoro)quinolones or to any of the excipients.

Do not use in animals that are epileptic or suffer from seizures since enrofloxacin may cause stimulation of the central nervous system.

6. ADVERSE REACTIONS

Digestive tract disorders (e.g. diarrhoea) may occur in very rare cases. These signs are generally mild and transient.
During the period of rapid growth, enrofloxacin may affect cartilage in joints.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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. Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Pet rabbits, rodents, ornamental birds and reptiles.

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

Instructions for use

To be administered by oral gavage.
Dosage
Owing to differences in physiology and pharmacokinetics (how the drug is processed in the body) between the wide range of target species, 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 veterinary surgeon, as safety at higher doses has not been investigated. To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

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

Rodents and pet rabbits
5 mg enrofloxacin per kg bodyweight (0.2 ml per kg bodyweight), twice daily for 7 days.

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

Reptiles are ectothermic (cold-blooded), relying on external heat sources to maintain their body temperature at the optimum level for correct function of all body systems. Body temperature has an important influence on metabolism (processing) of drugs and the activity of the immune system. Therefore, the veterinary surgeon must be aware of correct temperature requirements of the respective reptile species, as well as the hydration status of the individual patient. In addition, large differences exist in the pharmacokinetic behaviour of enrofloxacin (the active ingredient) among different species, which will influence the decision about the correct dosage of the 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), twice daily 7 days. Treatment should be re-evaluated if no improvement is seen. It is commonly advised to re-evaluate the treatment if no clinical improvement is observed within 3 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.

10 ml bottle: A 1 ml syringe is provided with the 10 ml bottle for withdrawal of small volumes of the product and to facilitate dilution prior to administration. This syringe has dosage graduations of 0.01 and 0.1 ml. The lowest volume that has been demonstrated to be accurate is 0.1 ml. Therefore, for accuracy of dosing, it is recommended to draw up a minimum of 0.1 ml of product.

30 and 50 ml bottles: A 5 ml syringe is provided for withdrawal of the product.

The diluted solution should be mixed thoroughly prior to administration.

The dilution should be made on a twice-daily basis immediately prior to provision, preferably in a glass container. Any unused solution should be disposed of immediately after use.

After extracting and expressing the amount of test product required the syringes should be washed with lukewarm water to remove any remaining product. The syringe can subsequently be used to prepare another solution or be opened, emptied and left to dry.

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.
Shelf life after first opening the immediate packaging: 28 days.
Keep the bottle tightly closed.
Shelf-life after dilution according to directions: use immediately

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

12. SPECIAL WARNINGS

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 instructions given in the package leaflet may increase the prevalence of bacteria resistant to 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.
Do not administer undiluted product. Ensure thorough mixing. Direct oral administration has been associated with buccal and pharyngeal necrosis. This veterinary medicinal product should be administered only as indicated in section “Advice on correct administration” (Amounts to be administered and administration route).

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to (fluoro)quinolones or to any of the excipients should avoid contact with the veterinary medicinal product.
The undiluted veterinary medicinal product is strongly alkaline and may cause irritation if it comes into contact with the skin or eyes.
Personal protective equipment consisting of impermeable gloves should be worn when handling the veterinary medicinal product.

Avoid skin and eye contact.
Wash any splashes from skin or eyes immediately with large amounts of water. If irritation persists, seek medical advice.
Wash hands after use.
Do not eat, drink or smoke whilst handling the product.

Pregnancy, lactation and lay:
Pet rabbits and rodents
Laboratory studies in rats and rabbits have not produced any evidence of physical effects in the developing embryo but have shown evidence of effects in the fetus at doses producing maternal toxicity. The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Ornamental birds and reptiles
The safety of the veterinary medicinal product has not been established during lay. Fluoroquinolones can have detrimental effects on developing eggs. Use only accordingly 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).
Do not use concurrently with theophylline as the elimination of theophylline may be delayed.
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.

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

Medicines should not be disposed of via wastewater.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2020

15. OTHER INFORMATION

Pharmacotherapeutic group: Antibacterials for systemic use, fluoroquinolones.
ATCvet code: QJ01MA90.

Pack sizes:

1 x 10 ml, 10 x (1 x 10 ml.)
1 x 30 ml, 10 x (1 x 30 ml).
1 x 50 ml, 10 x (1 x 50 ml).

Not all pack sizes may be marketed.

Approved: 26/02/21