ANNEX II

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Enrofloxacin 25 mg/ml

3. PHARMACEUTICAL FORM

Concentrate for oral solution.

4. PACKAGE SIZE

10 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(s):
Do not use in animals producing food intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

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 the product leaflet.

10. EXPIRY DATE

EXP {month/year}

Shelf life after first opening the immediate packaging: 28 days.
Once opened, use by _____.
Shelf life after dilution according to directions: in use shelf life for medicated drinking water is 12 hours.

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

Avimedical B.V.
Abbinkdijk 1
7255 LX Hengelo (Gld)
THE NETHERLANDS

16. MARKETING AUTHORISATION NUMBER(S)

Vm 43564/4001

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass bottle (10 ml and 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orniflox 25 mg/ml oral concentrate
Enrofloxacin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Enrofloxacin 25 mg/ml

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

10 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once opened, use by _____.
After dilution: in use shelf life for medicated drinking water is 12 hours.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Orniflox 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:
Avimedical B.V.
Abbinkdijk 1
7255 LX Hengelo (Gld)
THE NETHERLANDS

Manufacturer responsible for batch release:
Floris Veterinaire Producten B.V.
Kempenlandstraat 33
5262 GK Vught
THE NETHERLANDS

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orniflox 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 INGREDIENTS

Active substance:
Enrofloxacin 25 mg/ml

Excipient
Benzyl alcohol (E-1519) 18 mg/ml

Clear slightly yellow 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

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.

7. TARGET SPECIES

Pet rabbits, rodents, ornamental birds and reptiles.

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

Pet rabbits, rodents and reptiles
To be administered by oral gavage.

Ornamental birds
To be administered via medicated drinking water or by oral gavage (crop needle).

Dosage
Never administer undiluted product. Ensure thorough mixing.

Owing to differences in physiology and pharmacokinetics (how the drug is processed in the body) between the wide range of species for which this veterinary medicinal 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 veterinary surgeon, as safety at higher doses has not been investigated.

The uptake of medicated water depends on the clinical condition of the animals, the environment, the age and the kind of feed provided. In order to obtain the correct dosage, the concentration of enrofloxacin should be adjusted accordingly.

In order to ensure consumption of the medicated water, animals should not have access to other water supplies whilst being treated.

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

50 ml bottle: A 5 ml syringe is provided with the 50 ml bottles for withdrawal of product.

The diluted solution should be mixed thoroughly prior to administration.

Medicated drinking water should be freshly prepared and supplied immediately, preferably in a glass container, and replaced every 12 hours. Any medicated drinking water solution not consumed of after 12 hours should be disposed of.

The dilution prepared for direct administration should be made on a twice daily basis immediately prior to provision, preferably in a glass container. This dilution should be administered immediately. Any unused solution should be disposed of immediately after use.
After extracting and expressing the amount of veterinary medicinal 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(S)

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 tightly closed.
Do not use this veterinary medicinal product after the expiry date stated on the label and carton after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 28 days.
The in use shelf life for medicated drinking water is 12 hours.
Any remaining diluted solution should be discarded immediately after use.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

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 8 (DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION) and in section 9 (ADVICE ON CORRECT ADMINISTRATION).

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 SPC 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.

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

People with known hypersensitivity to fluoroquinolones or to any of the excipients should avoid any 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 veterinary medicinal product.

Pregnancy and lactation:

Mammals
Laboratory studies in rats and rabbits have not produced any evidence of physical effects in the developing embryo but have shown evidence of toxic 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 according to the benefit-risk assessment by the responsible veterinarian.

Lay:

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 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).
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

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

December 2020

15. OTHER INFORMATION

For any information about this Veterinary Medicinal Product, please contact the local representative of the Marketing Authorisation Holder.

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

Package (size)

1 x 10 ml, 10 x (1 x 10 ml).
1 x 50 ml, 10 x (1 x 50 ml).
Not all pack sizes may be marketed.

Approved 21 December 2020