PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrobactin 25 mg/ml concentrate for oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Enrofloxacin 25 mg

3. PACKAGE SIZE

10 ml
30 ml
50 ml

4. TARGET SPECIES

Rabbits (exclusively kept as pets), rodents, ornamental birds and reptiles.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Gastric use after dilution.

7. WITHDRAWAL PERIODS

Withdrawal periods: Do not use in rabbits producing food intended for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days, by…
Shelf life after dilution according to directions: use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Keep the bottle tightly closed.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Le Vet Beheer B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 41821/4026

15. BATCH NUMBER

Lot {number}

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

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Enrofloxacin 25 mg/ml

10 ml
30 ml
50 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days, by…
Shelf life after dilution according to directions: use immediately.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active substance:
Enrofloxacin 25 mg

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

Clear slightly yellow solution.

3. Target species

Rabbits (exclusively kept as pets), rodents, ornamental birds and reptiles.

4. Indications for use

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 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. Special warnings

Special precautions for safe use in the target species:
Official and local antimicrobial policies should be taken into account when the veterinary medicinal 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 veterinary medicinal 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".

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 and show the package leaflet or the label to the physician.
Wash hands after use.
Do not eat, drink or smoke whilst handling the veterinary medicinal product.

Pregnancy, lactation and lay:

Pet rabbits and rodents
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
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.
Use only according 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 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:
In cases of accidental overdose digestive tract disorders (e.g. vomiting, diarrhoea) and neurological disorders may occur.

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

7. Adverse events

Rabbits (exclusively kept as pets), rodents, ornamental birds and reptiles:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Digestive tract disorder (e.g. diarrhoea)[a]
Undetermined frequency (cannot be estimated from the available data):	Joint cartilage disorder[b]

[a] These signs are generally mild and transient.
[b] Articular cartilage may be affected during the period of rapid growth.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Instructions for use
Gastric use, 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 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 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), 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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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 the veterinary medicinal product.

30 and 50 ml bottles: A 5 ml syringe is provided for withdrawal of the veterinary medicinal 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 veterinary medicinal product. The syringe can subsequently be used to prepare another solution or be opened, emptied and left to dry.

10. Withdrawal periods

Do not use in rabbits 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 which is stated on the label and the carton after Exp. The expiry date refers to the last day of that month.

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

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 41821/4026

Pack sizes:
1 or 10 x cardboard box with 10 ml bottle, and 1 ml syringe.
1 or 10 x cardboard box with 30 ml bottle, and 5 ml syringe.
1 or 10 x cardboard box with 50 ml bottle, and 5 ml syringe.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

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

Local representatives and contact details to report suspected adverse events:
Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
United Kingdom
Tel: +44 (0) 1939 211200

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V

Gavin Hall

Approved: 01 June 2026