SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Enrofloxacin 25 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol (E-1519)	18 mg
Potassium hydroxide (for pH adjustment)	
Hydroxyethylcellulose	
Caramel aroma	
Water, purified	

Clear slightly yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

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

3.2 Indications for use for each target species

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.

3.3 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 CNS stimulation.

3.4 Special warnings

None.

3.5 Special precautions for use

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 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.
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 3.9 ‘Administration routes and dosage’.

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.

Special precautions for the protection of the environment:
Not applicable.

3.6 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or 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 teratogenic effects but have shown evidence of foetotoxic effects at maternotoxic doses.
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, although detrimental effects on developing eggs of avian scavengers have been reported when these birds ingest livestock meat from animals previously administered fluoroquinolones.
Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 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.

3.9 Administration routes and dosage

Instructions for use
Gastric use, by oral gavage.

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 veterinary medicinal 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.

Dosage
Owing to physiological and pharmacokinetic differences 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 veterinarian, as tolerance 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, 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), 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In cases of accidental overdose digestive tract disorders (e.g. vomiting, diarrhoea) and neurological disorders may occur.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01MA90

4.2 Pharmacodynamics

Mode of action
Two enzymes essential in DNA replication and transcription, DNA gyrase and topoisomerase IV, have been identified as the molecular targets of fluoroquinolones. Target inhibition is caused by non-covalent binding of fluoroquinolone molecules to these enzymes. Replication forks and translational complexes cannot proceed beyond such enzyme-DNA-fluoroquinolone complexes, and inhibition of DNA and mRNA synthesis triggers events resulting in a rapid, drug concentration-dependent killing of pathogenic bacteria. The mode of action of enrofloxacin is bactericidal and bactericidal activity is concentration dependent.

Antibacterial spectrum
Enrofloxacin is active against many Gram-negative bacteria such as *Escherichia coli, Klebsiella* spp., *Actinobacillus pleuropneumoniae, Pasteurella* spp. (e.g. *Pasteurella multocida*), *Bordetella* spp., *Proteus* spp., *Pseudomonas* spp., against Gram-positive

bacteria such as *Staphylococcus* spp. (e.g. *Staphylococcus aureus*) and against *Mycoplasma* spp. at the recommended therapeutic doses.

Types and mechanisms of resistance
Resistance to fluoroquinolones has been reported to arise from five sources, (i) point mutations in the genes encoding for DNA gyrase and/or topoisomerase IV leading to alterations of the respective enzyme, (ii) alterations of drug permeability in Gram-negative bacteria, (iii) efflux mechanisms, (iv) plasmid mediated resistance and (v) gyrase protecting proteins. All mechanisms lead to a reduced susceptibility of the bacteria to fluoroquinolones. Cross-resistance within the fluoroquinolone class of antimicrobials is common.

4.3 Pharmacokinetics

The pharmacokinetics of enrofloxacin are such that both oral and parenteral administration leads to similar serum levels. Enrofloxacin possesses a high distribution volume. Tissue levels 2 – 3 times higher than found in the serum have been demonstrated in laboratory animals and target species. Organs in which high levels can be expected are the lungs, liver, kidney, skin, bone and lymphatic system. Enrofloxacin also distributes into the cerebrospinal fluid, the aqueous humour and the foetus in pregnant animals.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.
Shelf life after dilution according to directions: use immediately.

5.3 Special precautions for storage

Keep the bottle tightly closed. Any remaining diluted solution should be discarded immediately after use.

5.4 Nature and composition of immediate packaging

10 ml, 30 ml, and 50 ml amber type III glass bottles closed with tamper-evident HDPE/LDPE screw caps with ring and colourless LDPE syringe insert in a carton box containing 10 ml, 30 ml and 50 ml respectively. A 1 ml dosing syringe is supplied with each 10 ml bottle, a 5 ml dosing syringe is supplied with each 30 and 50 ml bottle. Each bottle is packed in an individual carton.

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.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Le Vet Beheer B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 41821/4026

8. DATE OF FIRST AUTHORISATION

30 December 2015

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

April 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall

Approved: 01 June 2026