1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrocare 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

Excipient:
Benzyl Alcohol 14 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Concentrate for Oral Solution
Clear Solution

4. CLINICAL PARTICULARS

4.1 Target species

Pet rabbits, rodents, ornamental birds and reptiles.

4.2 Indications for use, specifying the 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.

4.3 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.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

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 SPC 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.

4.6 Adverse reactions (frequency and seriousness)

During the period of rapid growth, enrofloxacin may affect articular cartilage.

4.7 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.

4.8 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). The simultaneous application of substances containing aluminium, calcium or magnesium can impair the absorption of enrofloxacin.

4.9 Amounts to be administered and administration route

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.

Information 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

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

5. PHARMACOLOGICAL PROPERTIES

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

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

The pharmacokinetic properties 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium hydroxide
Benzyl alcohol
Hypromellose
Purified water

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months
Shelf life after first opening the immediate packaging: 90 days.
Shelf life after dilution: Any medicated liquid remaining 24 hours after preparation must be discarded.

6.4. Special precautions for storage

Keep the bottle in the outer carton.

6.5 Nature and composition of immediate packaging

20 and 100ml amber polyvinyl chloride bottles with a polypropylene self-sealing syringe adaptor and a child resistant polyethylene screw cap.

The 20ml presentation is packaged in a carton containing a 3ml polypropylene syringe and the 100ml presentation is packaged in a carton containing a 10ml polypropylene syringe.

Pack sizes: 20ml and 100ml

Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

8. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:
Date of renewal:

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE