

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **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**

1 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 case of confirmed or suspected resistance to quinolones, since a high degree of cross resistance between enrofloxacin and other quinolones exists.

Do not use in cases of known 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 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 should avoid contact with the product.

The product is an alkaline solution and may cause irritation if it comes into contact with the skin or eyes.

Wear impermeable gloves when administering the product.

Rinse any splashes from skin or eyes immediately with water.

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**

In the absence of data on its use in some of the target species, caution should be used when prescribing during these periods and a careful risk/benefit assessment made.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

None known.

#### **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 IMMUNOLOGICAL 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 Incompatibilities**

None known

### **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**

The bottle is to be stored in the 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**

Animalcare Ltd  
10 Great North Way  
York  
YO26 6RB  
UK

#### **8. MARKETING AUTHORISATION NUMBER**

Vm 10347/4041

#### **9. DATE OF FIRST AUTHORISATION**

01 June 2017

#### **10. DATE OF REVISION OF THE TEXT**

June 2017

**Approved: 01/06/2017**

