

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrocare 25 mg/ml Solution for Injection for Dogs, Cats, Rabbits, Rodents, Reptiles and Ornamental birds

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of solution for injection contains:

Active substance:mg

Enrofloxacin 25

Excipients:

Butyl alcohol as antimicrobial preservative 30

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

Clear light yellow, sterile, aqueous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs, cats, rabbits, rodents, reptiles and ornamental birds.

4.2 Indications for use, specifying the target species

Dogs

Treatment of infections of the alimentary, respiratory and urogenital tracts (including prostatitis, adjunctive antibiotic therapy for pyometra), skin and wound infections, otitis (externa/media) caused by enrofloxacin susceptible strains of: *Staphylococcus* spp., *Escherichia coli*, *Pasteurella* spp., *Klebsiella* spp., *Bordetella* spp., *Pseudomonas* spp. and *Proteus* spp.

Cats

Treatment of infections of the alimentary, respiratory and urogenital tracts (as adjunctive antibiotic therapy for pyometra), skin and wound infections, caused by enrofloxacin susceptible strains of: *Staphylococcus* spp., *Escherichia coli*, *Pasteurella* spp., *Klebsiella* spp., *Bordetella* spp., *Pseudomonas* spp. and *Proteus* spp.

Rabbits

Treatment of infections of the alimentary 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 alimentary 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

Do not use in cases of resistance against other fluoroquinolones, due to the potential for cross-resistance.

Do not use in dogs less than 1 year of age as damage to the articular cartilage may occur during the period of rapid growth, specifically in large breeds of dog. As a precaution very large breeds of dog should not be treated with the product until they are 18 months of age because of their longer growth period.

Do not use in cats less than 8 weeks of age.

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

Cats

Retinotoxic effects including blindness can occur when the recommended dose is exceeded.

Reptiles and ornamental birds

Muscle bruising after injection in reptiles and birds has been reported occasionally.

4.5 Special precautions for use

Special precautions for use in animals

Do not use for prophylaxis.

Do not exceed the recommended dosage.

Repeat injections should be made at different sites.

Do not use in dogs and cats with CNS disturbances.

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.

Official and local antimicrobial policies should be taken into account when the product is used.

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 is an alkaline solution. Wash any splashes from skin and eyes immediately with water.

People with known hypersensitivity to (fluoro)quinolones should avoid contact with this product.

Do not eat, drink or smoke whilst using the product.

In case of accidental self-injection seek medical advice immediately and show the package leaflet or label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Local tissue reactions may occur at the injection site. Normal sterile precautions should be taken.

4.7 Use during pregnancy, lactation or lay

There is no restriction on the use of this product during pregnancy and lactation of the bitch or queen.

In the absence of data on its use in some exotic 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 interactions

Care should be taken during the concomitant use of flunixin and enrofloxacin in dogs to avoid adverse drug reactions. The decrease in drug clearances as a result of co-administration of flunixin and enrofloxacin indicates that these substances interact during the elimination phase. Thus, in dogs, the co-administration of enrofloxacin and flunixin increased the AUC and the elimination half-life of flunixin and increased the elimination half-life and reduced the C_{max} of enrofloxacin.

4.9 Amounts to be administered and administration route

Subcutaneous or intramuscular use.

Repeated injections should be made at different injection sites.

To ensure a correct dosage, body weight (bw) should be determined as accurately as possible to avoid underdosing.

Dogs and cats

5 mg of enrofloxacin/kg bw, corresponding to 1 ml/5 kg bw, daily by subcutaneous injection for up to 5 days. Treatment may be initiated with injectable product and maintained with enrofloxacin tablets. Duration of treatment should be based on the duration of treatment approved for the appropriate indication in the product information of the tablet product.

Rabbits

10 mg/kg bw, corresponding to 2 ml/5 kg bw, once daily by subcutaneous injection for 5 to 10 consecutive days.

Rodents

10 mg/kg bw, corresponding to 0.4 ml/kg bw, once daily by subcutaneous injection for 5 to 10 consecutive days. If necessary, depending on the severity of clinical signs, this dosage can be doubled.

Reptiles

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 dependent on the body temperature. Therefore, the veterinarian must be aware of the 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 Enrocare 25mg/ml. Therefore, the recommendations made here can only be used as a starting point for individual dose setting.

5–10 mg/kg bw, corresponding to 0.2–0.4 ml/kg bw, once daily by intramuscular injection for 5 consecutive days. An extension of the treatment interval to 48 hours may be necessary in individual cases. In complicated infections, higher dosages and longer treatment courses may be necessary. The presence of the renal portal system in reptiles means it is prudent to administer substances in the front half of the body wherever possible.

Ornamental birds

20 mg/kg bw, corresponding to 0.8 ml/kg bw, once daily by intramuscular injection for 5 to 10 consecutive days. In case of complicated infections higher doses may be necessary.

The vial seal may be punctured up to a maximum of 25 times.

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

Do not exceed the recommended dose. In accidental overdose there is no antidote and treatment should be symptomatic.

In target animal studies, cats have been shown to suffer ocular damage after receiving doses of more than 15 mg/kg once daily for 21 consecutive days. Doses of 30 mg/kg given once daily for 21 consecutive days have been shown to cause irreversible ocular damage. At 50 mg/kg given once daily for 21 consecutive days, blindness can occur.

4.11 Withdrawal period(s)

Rabbits:

Meat and offal: 6 days.

Do not use in birds intended for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-infectives 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 pharmacokinetics of enrofloxacin in dogs and cats are such that oral and parenteral administration leads to similar serum levels. Enrofloxacin possesses a high distribution volume. Tissue levels 2-3 times higher than that 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

Butyl alcohol
Potassium hydroxide
Water for injections

6.2 Major incompatibilities

None known.

6.3 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

6.4 Special precautions for storage

Do not store above 25°C
Do not freeze.
Keep the vial in the outer carton in order to protect from light.
Discard unused material.

6.5 Nature and composition of immediate packaging

50 or 100 ml Amber Type I multidose glass vial with a grey bromobutyl rubber stopper and aluminium overseal.

50 ml vials sold in packs containing 1 x 50 ml, 6 x 50 ml or 12 x 50 ml cartons.
100 ml vials sold in packs containing 1 x 100 ml, 6 x 100 ml or 12 x 100 ml cartons.
Not all pack sizes may be marketed.

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

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

7 MARKETING AUTHORISATION HOLDER

Emdoka bvba
John Lijsenstraat 16
B-2321 Hoogstraten
Belgium

8 MARKETING AUTHORISATION NUMBER(S)

VPA10534/007/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20 May 2010

Date of last renewal: 22 May 2015

10 DATE OF REVISION OF THE TEXT

February 2019