Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrocare 50 mg/ml Solution for Injection for Cattle, Pigs, Dogs and Cats

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of the solution for injection contains:

Active substance:mg
Enrofloxacin 50

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

Cattle (calves)
Pigs weighing more than 25kg
Dogs and cats

4.2 Indications for use, specifying the target species

Calves
Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mannheimia haemolytica* and *Mycoplasma* spp.
Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis*.

Pigs
Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mycoplasma* spp. and *Actinobacillus pleuropneumoniae*.
Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.

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, e.g.: *Staphylococcus* spp., *Escherichia coli, Pasteurella* spp., *Klebsiella* spp., *Bordetella* spp., *Pseudomonas* spp. and *Proteus* spp.

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 under 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.
Do not use in growing horses because of possible deleterious damage on articular cartilage.

4.4 Special warnings for each target species

Cattle and pigs
None.

Dogs
None.

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

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.
Degenerative changes of articular cartilage were observed in calves treated orally with 30 mg enrofloxacin/kg bw during 14 days.
The use of enrofloxacin in growing lambs at the recommended dose for 15 days caused histological changes in the articular cartilage, not associated with clinical signs.
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 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)

Occasionally skin reactions have been seen after administration to kennelled greyhounds.
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.

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

Intravenous, 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.

Calves
5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily for 3-5 days.
Acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis:* 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily for 5 days.
The product can be administered by slow intravenous or subcutaneous administration.
Not more than 10 ml should be administered at one subcutaneous injection site.

Pigs
2.5 mg of enrofloxacin/kg bw, corresponding to 0.5 ml/10 kg bw, once daily by intramuscular injection for 3 days.
Alimentary tract infection or septicaemia caused by *Escherichia coli*: 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily by intramuscular injection for 3 days.
In pigs, the injection should be made in the neck at the ear base.
Not more than 3 ml should be administered at one intramuscular injection site.

Dogs and cats
5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 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 SPC of the tablet product.

The vial seal may be punctured up to a maximum of 25 times for the 100 ml vials, or 50 times for the 250ml vials.

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.

No target animal studies were performed in cattle. In pigs, no adverse effects were observed after administration of the product at 5 times the recommended therapeutic dose.

4.11 Withdrawal period(s)

Calves:
Following intravenous injection: Meat and offal: 5 days.
Following subcutaneous injection: Meat and offal: 12 days.
Not authorised for use in animals producing milk for human consumption.

Pigs:
Meat and offal: 13 days.

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*, *Mannheimia haemolytica*, *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

100 or 250 ml Amber Type I multidose glass vial with a grey bromobutyl rubber stopper and aluminium overseal.

100 ml vials sold in packs containing 1 x 100 ml, 6 x 100 ml or 12 x 100 ml cartons.
250 ml vials sold in packs containing 1 x 250 ml, 6 x 250 ml or 12 x 250 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)

VPA10534/007/002

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