Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrocat flavour 25 mg/ml oral suspension for cats

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Enrofloxacin 25 mg

Excipients:
Sorbic acid (E200) 1 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension
White to pale yellow suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cats

4.2 Indications for use, specifying the target species

For the treatment of single or mixed bacterial infections of the respiratory, digestive and urinary tract, otitis externa, skin and wound infections caused by the following enrofloxacin-sensitive Gram-positive and Gram-negative bacteria: *Staphylococcus* spp., *Escherichia coli, Haemophilus* spp. and *Pasteurella* spp.

4.3 Contraindications

Do not use in animals with existing impairment of cartilage growth.
Do not use in animals with a known history of seizures, since enrofloxacin may cause CNS stimulation.
Do not use in animals with known hypersensitivity to fluoroquinolones or any of the excipients.
Do not use in animals less than 8 weeks of age.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
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 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.
Official and local antimicrobial policies should be taken into account when the product is used.
In cases of pyoderma, possible underlying primary disease should be identified and treated.

Enrofloxacin is partially excreted via the kidneys; as with all fluoroquinolones, excretion may therefore be delayed in individuals with existing renal damage.
The product should be used with caution in animals with severe renal or hepatic impairment.
Retinotoxic effects including blindness can occur when the recommended dose is exceeded.
Do not use in cases of known resistance to quinolones or fluoroquinolones because of near-total cross-resistance to the former and complete cross-resistance to the latter.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
- Enrofloxacin and sorbic acid may cause hypersensitivity (allergic reactions). People with known hypersensitivity to enrofloxacin or to any of the excipients should avoid contact with the veterinary medicinal product.
- The veterinary medicinal product may be irritant to skin and eyes.
- Avoid dermal and eye contact with the product. In case of accidental dermal and/or eye contact, wash any splashes from skin or eyes immediately with water.
- Do not eat, drink or smoke while handling the product.
- Enrofloxacin may cause gastrointestinal effects such as abdominal pain and diarrhoea if ingested. To avoid accidental ingestion, particularly by a child, do not leave a syringe containing the solution in the sight or reach of children. The used syringe should be stored with the product in the original carton. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
- Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

On very rare occasions, mild and transient gastrointestinal disorders, such as hypersalivation, vomiting or diarrhoea, may be observed. As a result, anorexia may occur.
Hypersensitivity reactions can occur.
In very rare cases, neurological signs (seizures, tremors, ataxia, excitation) and anaphylactic reactions can also occur.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Laboratory studies in rats and chinchillas have not produced any evidence of a teratogenic, foetotoxic or, maternotoxic effects.
As the safety has not been assessed in pregnant cats and enrofloxacin passes into the maternal milk, the use is not recommended during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interactions

Combination of the product (enrofloxacin) with chloramphenicol, macrolide antibiotics or tetracyclines may produce antagonistic effects.
The concomitant administration of substances containing magnesium or aluminium may reduce the absorption of enrofloxacin. These drugs should be administered two hours apart.
Concomitant administration of theophylline requires careful monitoring as serum levels of theophylline may increase.
The concomitant use with digoxin should be avoided as fluoroquinolones can increase the bioavailability of digoxin.
Concurrent administration of fluoroquinolones may increase the action of oral anticoagulants.
Concomitant administration of fluoroquinolones in combination with non-steroidal anti-inflammatory drugs (NSAID) in animals could lead to seizures because of potential pharmacodynamic interactions in the CNS.
In animals subjected to rehydration, avoid excessive alkalinity of the urine.

4.9 Amounts to be administered and administration route

Oral use.
The product should be administered directly onto the back of the tongue and not in the animal's feed.
The dosage is 5 mg enrofloxacin per kg bodyweight once daily for 5 consecutive days. This is equivalent to 0.2 ml of the veterinary medicinal product per kg bodyweight once daily for 5 consecutive days.
In chronic and severe diseases, the duration of treatment can be extended up to 10 days.

Treatment should be reconsidered if no improvement of the condition is observed after 3 days of treatment.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid over- or underdosing.
Do not exceed the recommended dosage.
Figure 1: Administration of the product

Shake well for 15 seconds before use

Draw out the appropriate dosage into the syringe

Administer directly onto the back of the tongue

In order to avoid cross-contamination, the same syringe should not be used for different animals. Thus, one syringe should only be used for one animal. After administration the syringe should be cleaned with tap water and stored in the carton box together with the product.
A 3 ml syringe with 0.1 ml graduations is supplied with every package of the product.

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

Do not exceed the recommended dosage. In the event of overdosing digestive tract disorders (vomiting, diarrhoea or hypersalivation) or CNS alterations (mydriasis, ataxia) may occur. In severe cases it may be necessary to interrupt the treatment.

Cats have been shown to suffer ocular damage after receiving doses higher than recommended. At doses of 20 mg/kg bw/day or higher, the toxic effects on the retina could lead to irreversible blindness in the cat.
To reduce the absorption of enrofloxacin taken orally the administration of antacids containing magnesium or aluminium is recommended.

4.11 Withdrawal period(s)

Not applicable

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, fluoroquinolones
ATC vet 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 has antimicrobial activity against the following enrofloxacin-sensitive Gram-positive and Gram-negative bacteria: *Staphylococcus* spp., *Escherichia coli, Haemophilus* spp., and *Pasteurella* spp.

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. The Clinical and Laboratory Standard Institute (CLSI) has established veterinary breakpoints for enrofloxacin to enable internationally harmonised evaluation of MIC (Minimum Inhibitory Concentration) data.
For cats CLSI has established the enrofloxacin breakpoints S: ≤ 0.5 µg/ml, I: 1-2 µg/ml and R: ≥ 4 µg/ml for skin and soft tissue infections.

5.2 Pharmacokinetic particulars

Enrofloxacin shows an overall high oral availability of >80%.

After oral administration, the maximum concentration of active substance is reached after approximately one hour.

Fluoroquinolones diffuse to a great extent into body fluids and tissues, achieving higher concentrations than those found in plasma. Moreover, they are widely distributed in skin, bones and semen, reaching the anterior and posterior eye chambers; they cross the placenta and the brain barrier. They also accumulate in phagocytes (alveolar macrophages, neutrophils). Protein binding of enrofloxacin in serum is 40%.

Metabolism varies between species and it is around 50-60%. Biotransformation of enrofloxacin at hepatic level gives rise to an active metabolite which is ciprofloxacin.

Excretion occurs via bile and the kidneys, with the latter being the main route. Renal excretion is carried out by glomerular filtration and also by active tubular secretion through organic anion pumps.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbic acid (E200)
Carmellose sodium
Xanthan gum
Polysorbate 80
Beef flavour
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: 2 years
Shelf life after first opening the immediate packaging: 1 month

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

High density polyethylene (HDPE) bottles sealed with a child resistant stopper made of polypropylene (PP) with thread and low density polyethylene (LDPE) plug with a polypropylene oral dosing syringe with an HDPE barrel.

Package size:
Cardboard box of 1 bottle of 8.5ml and a 3 ml oral syringe

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

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Av. Universitat Autònoma, 29
08290 Cerdanyola des Vallès
Barcelona
E-08950
Spain

8 MARKETING AUTHORISATION NUMBER(S)

VPA10425/010/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th May 2020

10 DATE OF REVISION OF THE TEXT