Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrotron Flavour 150 mg Tablets for dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 tablet contains

Active substance(s):
Enrofloxacin 150.0 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet
White to off-white, round tablet with one breakline and one decorative line. The tablet can be divided into two equal parts.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs

4.2 Indications for use, specifying the target species

For the treatment of bacterial single or combined infections of the respiratory, alimentary or urinary tract, the skin or wounds, caused by Enrofloxacin-sensitive gram-negative and gram-positive bacteria: *E. coli, Pasteurella* spp., *Haemophilus* spp. and staphylococci.

4.3 Contraindications

Do not use in young or growing dogs (dogs aged less than 12 months (small breed) or less than 18 months (large breed)) as the product may cause epiphyseal cartilage alterations in growing puppies.
Do not use in dogs having seizure disorders, since enrofloxacin may cause CNS stimulation.
Do not use in dogs with known hypersensitivity to fluoroquinolones or to any of the excipients of the product.
Do not use in case of resistance to quinolones, as there exists almost complete cross resistance to other quinolones and complete cross resistance to other fluoroquinolones.
Do not use with tetracyclines, phenicols or macrolides because of potential antagonistic effects.
See also section 4.7

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.
Skin infections are mostly secondary to an underlying disease. It is advisable to determine the underlying cause and to treat the animal accordingly.
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 fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential cross resistance.
As enrofloxacin is metabolized by the liver and partly eliminated via the kidneys, elimination may be delayed in dogs with liver or renal disturbances. Therefore, in cases of known liver or renal impairment, the product should be used with caution.
The chewable tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
People with known hypersensitivity to fluoroquinolones should avoid contact with the veterinary medicinal product.
Wash hands after use.
In case of contact with the eyes, wash immediately with plenty of clean water.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

In rare cases vomiting and diarrhoea are observed.
See section 4.3.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports)

4.7 Use during pregnancy, lactation or lay

Pregnancy:
Do not use during pregnancy.

Lactation:
Do not use during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Concurrent use of flunixin should be under careful veterinary monitoring, as the interactions between these drugs may lead to adverse events related to delayed elimination.
Elimination of theophylline may be delayed.
Antagonistic effect may occur if enrofloxacin is combined with phenicols, macrolide antibiotics or tetracyclines.
Substances containing magnesium or aluminium, if administered at the same time, may impair the enrofloxacin resorption.

4.9 Amounts to be administered and administration route

Tablet for oral use.
Dose: 5 mg enrofloxacin per kg body weight (BW) daily, corresponding to:
½ tablet for 15 kg body weight
1 tablet per 30 kg body weight.

Can be administered directly or given with food.
Treatment generally takes place over 5 - 10 consecutive days.

If there is no clinical improvement within 3 days, the sensitivity test is to be repeated and it may be necessary to switch to a different treatment.
The recommended doses should not be exceeded.

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

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

Overdosing can cause vomiting and nervous signs (muscle tremor, incoordination and convulsions) which may require treatment discontinuation.
In the absence of any known antidote, apply drug elimination methods and symptomatic treatment.
If necessary, administration of aluminium- or magnesium-containing antacids or activated carbon can be used to reduce absorption of enrofloxacin.
According to literature, signs of overdose with enrofloxacin in dogs such as inappetence and gastrointestinal disturbance were observed at approximately 10 times the recommended dose when administered for two weeks. No signs of intolerance were observed in dogs administered 5 times the recommended dose for a month.

4.11 Withdrawal Period(s)

Not applicable

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: fluoroquinolone group gyrase inhibitor
ATCvet code: QJ 01 MA 90

5.1 Pharmacodynamic properties

Enrofloxacin is a synthetic fluoroquinolone antibiotic that exerts its activity by inhibiting topoisomerase II, an enzyme involved in the mechanism of bacterial replication.

Enrofloxacin exerts bactericidal activity concentration-dependant with similar values of minimal inhibit concentration and minimal bactericide concentrations. It also possesses activity against bacteria in the stationary phase by an alteration of the permeability of the outer membrane phospholipid cell wall.

Enrofloxacin is active against a wide range of Gram negative bacteria, against mycoplasmas and against many Gram positive bacteria.

Pseudomonas aeruginosa is variably susceptible and, when it is susceptible, usually has a higher MIC than other susceptible organisms.

Induction of resistance against quinolones can develop by mutations in the gyrase gene of bacteria and by changes in cell permeability towards quinolones.

5.2 Pharmacokinetic properties

Enrofloxacin is rapidly metabolised to form an active compound, ciprofloxacin.

After oral administration of ENROTRON FLAVOUR 150 mg (5 mg/kg) in dogs:

- *The maximal plasma concentration of enrofloxacin of 1205.48 ng/mL was observed 1.42 hours following administration.*
- *The maximal plasma concentration of ciprofloxacin (432.48 ng/mL) was observed 2.6 hours following administration.*

Enrofloxacin is primarily excreted via the kidneys. A major portion of the parent drug and its metabolites is recovered in urine.
Enrofloxacin is widely distributed in the body. The tissue concentrations are often higher than the serum concentrations. Enrofloxacin crosses the blood-brain barrier. The degree of protein binding in serum is 14 % in dogs. In dogs (5 mg/kg), the half-life for enrofloxacin in serum is 2.73 hours and the half-life for ciprofloxacin is 5.35 hours. Approximately 60 % of the dose is excreted as unchanged enrofloxacin and the remainder as metabolites, amongst others ciprofloxacin. The enrofloxacin clearance is approximately 28.2 ml/minute/kg bodyweight in dogs and the ciprofloxacin clearance is approximately 30.8 ml/minute/kg bodyweight in dogs.
Bioavailability is in excess of 80 %.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Cellulose, powdered
Maize starch
Povidone 25
Silica, colloidal anhydrous
Magnesium stearate
Beef Flavour

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale (Aluminium-aluminium blister): 3 years.
Shelf-life of the veterinary medicinal product as packaged for sale (PVC-aluminium blister): 18 months.
Shelf-life of divided tablets: 72 hours.

6.4 Special precautions for storage

Store in the original package in order to protect from light.
Divided tablets should be returned to the original package.
Do not store above 30 °C.

6.5 Nature and composition of immediate packaging

10, 20, 30, 50, 100 tablets packed in blisters of 10 tablets consisting either of PVC / Aluminium foils or Aluminium / Aluminium foils.
Cardboard box containing 1, 2, 3, 5, 10 blisters.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

aniMedica GmbH
Im Südfeld 9
D-48308 Senden-Bösensell
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10826/011/002

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th November 2010

Date of last renewal: 25th November 2015

10 DATE OF REVISION OF THE TEXT