SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrotron 25 mg/ml oral solution for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substance:
Enrofloxacin 25.0 mg
Excipients:
Benzyl alcohol (E-1519) 14.0 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution
Clear slightly yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (calves)

4.2 Indications for use, specifying the target species

Treatment of infections of the respiratory and alimentary tract caused by enrofloxacin-sensitive microorganisms.
In particular:

- Treatment of neonatal diarrhoea and septicaemia caused by enrofloxacin-sensitive *E. coli.*
- Treatment of respiratory infections caused by enrofloxacin-sensitive *Pasteurella multocida*, *Mannheimia haemolytica* and *Mycoplasma bovis.*

To be used where clinical experience and/or sensitivity testing indicates enrofloxacin as the drug of choice.

4.3 Contraindications

Do not use in case of confirmed or suspected resistance to quinolones, since a high degree of cross resistance between enrofloxacin and other (fluoro)quinolones does exist.
Do not use in cases of hypersensitivity to the active substance, to other (fluoro)quinolones or to any of the excipients.
Do not use in cases of disturbances to the growth of cartilage and/or during injury to the locomotory system particularly if functionally loaded or body weight loaded joints are affected.
Do not use for prophylaxis.

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.
Wherever possible, fluoroquinolones should be used based on susceptibility testing.
Use of the veterinary medicinal 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.
During the period of rapid growth, enrofloxacin may affect articular cartilage.
Calves which only receive roughage should not be treated orally but by means of injection.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
People with known hypersensitivity to (fluoro)quinolones should avoid contact with the veterinary medicinal product.
Avoid skin and eye contact.
Direct contact with the skin should be avoided because of sensitisation, possible hypersensitivity reactions and contact dermatitis.
Wear gloves for this purpose.
Rinse any splashes from skin or eyes immediately with water.
Wash hands and exposed skin after use.
Do not smoke, eat or drink whilst using the veterinary medicinal product.

4.6 Adverse reactions (frequency and seriousness)

Gastrointestinal disturbances may rarely occur (more than 1 but less than 10 animals in 10000 animals).

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

Concurrent administration of enrofloxacin with other antimicrobials, tetracyclines and macrolide antibiotics may result in antagonistic effects. Absorption of enrofloxacin may be reduced if the veterinary medicinal product is administered together with substances containing magnesium or aluminium.
Do not combine enrofloxacin with steroidal anti-inflammatory products.

4.9 Amounts to be administered and administration route

For oral administration.

Dosage

2.5 mg enrofloxacin per kg bodyweight (equivalent to 5 ml per 50 kg bodyweight) daily for 3 to 5 days.
In case of complicated infections: 5 mg per kg bodyweight (equivalent to 10 ml per 50 kg bodyweight) daily for 5 days.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

The intake of the reconstituted veterinary medicinal product depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of enrofloxacin has to be adjusted accordingly.
Medicated drinking water should be replaced every 24 hours.

Administration route

To be administered orally either directly or with water, milk, milk replacer or electrolyte solution.

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

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

4.11 Withdrawal period(s)

Meat and offal: 7 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: quinolone and quinoxaline antibacterials, fluoroquinolones.
ATCvet code: QJ01MA90

5.1 Pharmacodynamic properties

Enrofloxacin belongs to the chemical class of fluoroquinolones. It exerts its bactericidal effect by interaction with the A subunit of the DNA gyrase. The DNA gyrase is a topoisomerase, which controls the bacterial replication (catalyses the supercoiling of chromosomal DNA strands).
Fluoroquinolones also possess activity against bacteria in the stationary phase by an alteration of the permeability of the cell membrane.
For enrofloxacin, the inhibitory and bactericidal concentrations are very close to each other; they are identical or differ by one or two dilution steps.

At low concentrations enrofloxacin possesses antimicrobial activity against most gram-negative bacteria, against many gram-positive bacteria and against mycoplasmas.
Resistance to fluoroquinolones occurs primarily by alteration in bactericidal cell wall penetration. Permeability changes occur either via decreased permeability of the hydrophilic pores or through alteration of the active transport (efflux) pump, thereby decreasing the intracellular content of fluoroquinolones.
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 peak concentration in serum is reached 2 – 4 hours after oral administration of the solution. Serum concentration in µg/ml relates in terms of numbers to ¼ - ½ of the administered dose in mg/kg.
In new born and young calves the absorption is faster and the serum peak higher.
Only 23 % of enrofloxacin is bound to serum protein. The active substance distributes in all tissues. Concentration in urine, bile, lung, liver and kidney exceed serum concentrations considerably.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol E-1519
Potassium hydroxide (for pH adjustment)
Hypromellose
Hydrochloric acid, dilute (for pH adjustment)
Water, purified

6.2 Major incompatibilities

In 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: 3 years
Shelf life after first opening the immediate packaging: 3 months
Shelf life after dilution or reconstitution according to directions: 24 hours

6.4 Special precautions for storage

Keep the bottle tightly closed.
After dilution, do not expose to direct daylight.

6.5 Nature and composition of immediate packaging

100 ml / 500 ml opaque polyethylene bottle with opaque polyethylene tamper evident screw cap and polypropylene measuring pitcher.
1 x 100 ml, 12 x 100 ml and 6 x 500 ml bottles are presented in a cardboard box.
Pack sizes: 1 x 100 ml; 1 x 500 ml 12 x 100 ml, 6 x 500 ml.

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

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 24745/4021

9. DATE OF FIRST AUTHORISATION

20 June 2013

10. DATE OF REVISION OF THE TEXT

July 2018

Approved: 25 July 2018