Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrotron 5 mg/ml oral solution for pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:
Active substance:
Enrofloxacin 5.0 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

Pigs (piglets)

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* spp.
- Enzootic pneumonia

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

4.3 Contraindications

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.

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.
Do not use in case of confirmed or suspected resistance to quinolones, since a high degree of cross resistance between enrofloxacin and other quinolones does exist.
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.
Susceptibility testing should be performed before treatment is initiated.
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.
Do not use for prophylaxis.
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.
Rinse any splashes from skin or eyes immediately with water.
Wash hands and exposed skin after use.
Do not eat, drink or smoke whilst using the veterinary medicinal product.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interactions

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
1.7 mg enrofloxacin per kg bodyweight daily for 3 to 5 days; equivalent to 1 ml per 3 kg bodyweight.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.
Administration route
The veterinary medicinal product is administered orally directly into the mouth of the animals using the dispenser.
The dosing pump of the dispenser delivers 1 ml per pump stroke.

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 or IMMUNOLOGICAL 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.
Consequently, the product is effective in primary or secondary infections with these microorganisms.
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.

5.2 Pharmacokinetic particulars

In pigs peak concentration in serum is reached 1 – 2 hours after oral administration of enrofloxacin.
This concentration in µg/ml relates in terms of numbers to 1/3 of the administered dose in mg/kg. Absorption in new born and young piglets is faster than in older piglets
The concentration of the active ingredient in the intestinal wall is higher than that found in the plasma.

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.

6.4 Special precautions for storage

Keep the bottle tightly closed.
Discard unused material.

6.5 Nature and composition of immediate packaging

100 ml, 250 ml opaque polyethylene bottle with opaque polyethylene temper evident screw cap and white pump dispenser which are presented in a cardboard box as well as the 12 x 100 ml and 6 x 250 ml sizes.
Pack sizes: 1 x 100 ml; 12 x 100 ml; 1 x 250 ml; 6 x 250 ml.

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 product should be disposed of in accordance with local / national requirements.

7 MARKETING AUTHORISATION HOLDER

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA10826/016/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st June 2013
Date of last renewal: 6th April 2018

10 DATE OF REVISION OF THE TEXT

April 2018