

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrotron 5 mg/ml oral solution for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Enrofloxacin 5.0 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Benzyl alcohol (E-1519)	14.0 mg
Potassium hydroxide (for pH adjustment)	
Hypromellose	
Hydrochloric acid, dilute (for pH adjustment)	
Water, purified	

Clear slightly yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (piglet)

3.2 Indications for use for each 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.

3.3 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.

Do not use in cases of confirmed or suspected resistance to quinolones, since a high degree of cross resistance between enrofloxacin and other quinolones does exist.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the product should be in accordance with official, national and regional antimicrobial policies.

The use of 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 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.

Not for 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, such as Enrofloxacin 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to

either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Not applicable.

3.8 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 veterinary medicinal products.

3.9 Administration routes and dosage

Oral use.

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.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 7 days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ01MA90

4.2 Pharmacodynamics

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.

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 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.

5.3 Special precautions for storage

Keep the bottle tightly closed.

5.4 Nature and composition of immediate packaging

Opaque polyethylene bottle with opaque polyethylene temper evident screw cap and pump dispenser in a cardboard box.

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.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

aniMedica GmbH

7. MARKETING AUTHORISATION NUMBER

Vm 24745/4020

8. DATE OF FIRST AUTHORISATION

20 June 2013

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

August 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 11 September 2026