SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrotron 50 mg/ml Solution for injection for cattle, sheep, goats, pigs, dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Enrofloxacin 50.0 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
1-Butanol	30.0 mg
Potassium Hydroxide (excipient and for pH adjustment)	
Hydrochloric acid (for pH adjustment)	
Water for Injections	

Clear, slightly yellowish to yellowish orange solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (calves), Sheep, Goats, Pigs, Dogs, Cats

3.2 Indications for use for each target species

Cattle (calves)
Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mannheimia haemolytica* and *Mycoplasma* spp.
Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of
Mycoplasma bovis.

Sheep
Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli.*

Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli.*
Treatment of mastitis caused by enrofloxacin susceptible strains of *Staphylococcus aureus* and *Escherichia coli.*

Goats
Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida* and *Mannheimia haemolytica*.
Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli.*
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of mastitis caused by enrofloxacin susceptible strains of *Staphylococcus aureus* and *Escherichia coli.*

Pigs
Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida*, *Mycoplasma* spp. and *Actinobacillus pleuropneumoniae*.
Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.

Dogs
Treatment of infections of the alimentary, respiratory and urogenital tracts (including prostatitis, adjunctive antibiotic therapy for pyometra), skin and wound infections, otitis (externa/media) caused by enrofloxacin susceptible strains of *Staphylococcus* spp.*, Escherichia coli, Pasteurella* spp.*, Klebsiella* spp.*, Bordetella* spp.*, Pseudomonas* spp. and *Proteus* spp.

Cats
Treatment of infections of the alimentary, respiratory and urogenital tracts (as adjunctive antibiotic therapy for pyometra), skin and wound infections, caused by enrofloxacin susceptible strains of, e.g.: *Staphylococcus* spp.*, Escherichia coli, Pasteurella* spp.*, Klebsiella* spp.*, Bordetella* spp.*, Pseudomonas* spp. and *Proteus* spp.

3.3 Contraindications

Do not treat dogs under 1 year of age with the veterinary medicinal product as damage to the articular cartilage may occur during the period of rapid growth, specifically in large breeds of dogs. As a precaution do not treat very large breeds of dog with the veterinary medicinal product until they are 18 months of age because of their longer growth period.
Do not use in cats less than 8 weeks of age.
Do not use for prophylaxis.
Do not use in animals that are epileptic or suffer from seizures since enrofloxacin may cause CNS stimulation. Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use when resistance / cross resistance to (fluoro)quinolones is known to occur. Refer to section 3.5.

Do not use in growing horses because of possible deleterious damage on articular cartilage.

3.4 Special warnings

In dogs enrofloxacin may affect articular cartilage during the period of rapid growth.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Enrofloxacin should be used with caution in epileptic animals or animals affected by renal dysfunction.

Official and local antimicrobial policies should be taken into account when the veterinary medicinal 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.
Whenever possible, fluoroquinolones should only be used based on susceptibility testing.
Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.

Degenerative changes of articular cartilage were observed in calves treated orally with 30 mg enrofloxacin/kg bw during 14 days.
The use of enrofloxacin in growing lambs at the recommended dose for 15 days caused histological changes in the articular cartilage, not associated with clinical signs.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The veterinary medicinal product is an alkaline solution. Direct contact with skin should be avoided due to sensitisation, contact dermatitis and possible hypersensitivity reactions to (fluoro)quinolones. Wear gloves. In case of eye or skin contact, rinse immediately with water. Do not eat, drink or smoke whilst handling the veterinary medicinal product.
Care should be taken to avoid accidental self-injection. If accidental self injection occurs seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle (calves), Sheep, Goats, Pigs, Dogs, Cats

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction[1] Digestive tract disorder (e.g. Diarrhoea)[2]
Undetermined frequency, (cannot be estimated from the available data):	Injection site inflammation[3], injection site reaction (e.g. Oedema)[4]

[1] In calves; transient local tissue reactions may be observed up to 14 days.
[2] Generally mild and transient.
[3] In pigs; after intramuscular administration; may persist up to 28 days after the injection.
[4] In dogs; moderate and transient.

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

Pregnancy and lactation:

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effects but have shown evidence of foetotoxic effects at maternotoxic doses.

Mammals
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Antagonistic effects due to concurrent administration of macrolides, tetracyclines and phenicols may occur. Enrofloxacin may interfere with the metabolism of theophylline, decreasing theophylline clearance resulting in increased plasma levels of theophylline. Care should be taken during the concomitant use of flunixin and enrofloxacin in dogs to avoid adverse drug reactions. The decrease in drug clearances as a result of co-administration of flunixin and enrofloxacin indicates that these substances interact during the elimination phase. Thus, in dogs, the co-administration of enrofloxacin and flunixin increased the AUC and the elimination half-life of flunixin and increased the elimination half-life and reduced the C_{max} of enrofloxacin.

3.9 Administration routes and dosage

Intravenous, subcutaneous or intramuscular use.
Repeated injections should be made at different injection sites.

To ensure a correct dosage, body weight (bw) should be determined as accurately as possible.

Cattle (calves):
5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily for 3-5 days.
Acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis*: 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily for 5 days.
The veterinary medicinal product can be administered by slow intravenous or subcutaneous administration.
Not more than 10 ml should be administered at one subcutaneous injection site.

Sheep and goats:
5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily by subcutaneous injection for 3 days. Not more than 6 ml should be administered at one subcutaneous injection site.

Pigs:
2.5 mg of enrofloxacin/kg bw, corresponding to 0.5 ml/10 kg bw, once daily by intramuscular injection for 3 days.
Alimentary tract infection or septicaemia caused by *Escherichia coli*: 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily by intramuscular injection for 3 days.
In pigs, the injection should be made in the neck at the ear base.
Not more than 3 ml should be administered at one intramuscular injection site.

Dogs and cats:
5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, daily by subcutaneous injection for up to 5 days.
Treatment may be initiated with injectable veterinary medicinal product and maintained with enrofloxacin tablets. Duration of treatment should be based on the duration of treatment approved for the appropriate indication in the SPC of the tablet veterinary medicinal product.

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

Do not exceed the recommended dosage. In accidental overdose there is no antidote and treatment should be symptomatic.
In target animal studies, cats have been shown to suffer ocular damage after receiving doses of more than 15 mg/kg once daily for 21 consecutive days. Doses of 30 mg/kg given once daily for 21 consecutive days have been shown to cause irreversible ocular damage. At 50 mg/kg given once daily for 21 consecutive days, blindness can occur.
In dogs and cats, lack of appetite and nausea may occur following overdose.
Overdose may result in CNS and renal dysfunction. In dogs, 10-fold over dosage results in neurological symptoms such as ataxia, tremor, nystagmus or convulsions. These symptoms are reversible on cessation of treatment.
No signs of over dosage were observed in pigs following administration of the veterinary medicinal product at five times the recommended therapeutic dose.
In cattle, sheep and goats, overdose has not been documented.

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

Cattle (calves):
Following intravenous injection: Meat and offal: 5 days.
Following subcutaneous injection: Meat and offal: 12 days.
Not authorised for use in animals producing milk for human consumption.

Sheep:
Meat and offal: 4 days.
Milk: 3 days.

Goats:
Meat and offal: 6 days.
Milk: 4 days.

Pigs:
Meat and offal: 13 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01MA90.

4.2 Pharmacodynamics

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 noncovalent 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 is active against many Gram-negative bacteria such as *Escherichia coli, Klebsiella* spp.*, Actinobacillus pleuropneumoniae, Mannheimia haemolytica, Pasteurella* spp. (e.g. *Pasteurella multocida*), *Bordetella* spp.*, Proteus* spp.*, Pseudomonas* spp., against Gram-positive bacteria such as *Staphylococcus* spp. (e.g. *Staphylococcus aureus*) and against Mycoplasma spp. at the recommended therapeutic doses.

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

Enrofloxacin is rapidly absorbed after parenteral injection. Bioavailability is high (approximately 100 % in pigs and cattle) with a low to moderate plasma protein binding (approximately 20 to 50 %). Enrofloxacin is metabolised to the active substance ciprofloxacin at approximately 40 % in dogs and ruminants, less than 10 % in pigs and cats.

Enrofloxacin and ciprofloxacin distribute well into all target tissues, e.g. lung, kidney, skin, and liver, reaching 2- to 3-fold higher concentrations than in plasma. Parent substance and active metabolite are cleared from the body via urine and faeces. Accumulation in plasma does not occur following a treatment interval of 24 h.
In milk, most of drug activity relates to ciprofloxacin. Overall drug concentrations peak at 2 hours after treatment showing an approximately 3-fold higher total exposure over the 24 hours dosing interval compared to plasma.

	Dogs	Cats	Pigs	Pigs	Cattle	Calves
Dose rate (mg/kg bw)	5	5	2.5	5	5	5
Route of administration	SC	SC	IM	IM	IV	SC
T_{max} (h)	0.5	2	2	2	-	1.2
C_{max} (µg/ml)	1.8	1.3	0.7	1.6	-	0.73
AUC (µg x h/ml)	-	-	6.6	15.9	7.11	3.09
Terminal half-life (h)	-	-	13.12	8.10	-	2.34
Elimination half-life (h)	4.4	6.7	7.73	7.73	2.2	-
F (%)	-	-	95.6	-	-	-

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: 28 days.

5.3 Special precautions for storage

Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

100 ml clear glass vial type I with Teflon coated rubber stopper sealed with an aluminium cap.

Pack sizes:
1 x 100 ml in a carton
12 x 100 ml in a carton

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 or household waste.

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 24745/4030

8. DATE OF FIRST AUTHORISATION

6 March 2012

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

May 2025

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: 27 October 2025