PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrotron 50 mg/ml Solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance

Enrofloxacin	50.0 mg

3. PACKAGE SIZE

100 ml
12 x 100 ml

4. TARGET SPECIES

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

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle (calves): intravenous or subcutaneous use.
Sheep, goats, dogs and cats: subcutaneous use.
Pigs: intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle (calves):
i.v.: Meat and offal: 5 days.
s.c.: Meat and offal: 12 days.
Not authorized 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.

8. EXPIRY DATE

Exp {mm/yyyy}
Once broached, use within 28 days.
Once broached, use by…..

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

aniMedica GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 24745/4030

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrotron 50 mg/ml Solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance

Enrofloxacin	50.0 mg

3. TARGET SPECIES

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

4. ROUTES OF ADMINISTRATION

Cattle (calves): **i.v.** or **s.c.** use.
Sheep, goats, dogs and cats: **s.c.** use.
Pigs: **i.m.** use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle (calves):
i.v.: Meat and offal: 5 days.
s.c.: Meat and offal: 12 days.
Not authorized 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.

6. EXPIRY DATE

Exp {mm/yyyy}
Once broached, use within 28 days.
Once broached, use by…..

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

aniMedica GmbH

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active substance:
Enrofloxacin 50.0 mg

Excipient:
1-Butanol 30.0 mg

Clear, slightly yellowish to yellowish orange solution.

3. Target species

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

4. Indications for use

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.

5. 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 “Special warnings”.
Do not use in growing horses because of possible deleterious damage on articular cartilage.

6. Special warnings

Special precautions for safe use in the target species:
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.
Enrofloxacin should be used with caution in epileptic animals or animals affected by renal dysfunction.

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

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 due 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 injection occurs seek medical advice immediately and show the package leaflet or the label to the physician.

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.

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.

Overdose:
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.

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

7. 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 (swelling))[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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system at https://www.gov.uk/report-veterinary-medicine-problem.

8. Dosage for each species, routes and method of administration

Intravenous (**i.v.**), subcutaneous (**s.c.**) or intramuscular (**i.m.**) use.
Repeated injections should be made at different injection sites.

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 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 product.

9. Advice on correct administration

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

10. 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.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on carton and vial after “Exp”. The expiry date refers to the last day of that month.
Keep the vial in the outer carton in order to protect from light.
Shelf life after first opening the immediate packaging: 28 days.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 24745/4030

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

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Manufacturer responsible for batch release:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Industrial Veterinaria, S.A.
Esmeralda 19
08950 Esplugues de Llobregat (Barcelona)
Spain

Local representatives and contact details to report suspected adverse events:
FORTE Healthcare Limited
Block 3, Unit 9
CityNorth Business Campus
Stamullen, Co.
Meath. K32 D990
Republic of Ireland
Tel.: +353 1 841 7666
E-Mail: pharmacovigilance@fortehealthcare.com

17. Other information

POM-V	Veterinary medicinal product subject to prescription

Gavin Hall
Approved: 27 October 2025