PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrotron 100 mg/ml Solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance
Enrofloxacin 100 mg

3. PACKAGE SIZE

100 ml
12 x 100ml
250 ml
12 x 250 ml

4. TARGET SPECIES

Cattle, Sheep, Goats, Pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle: intravenous or subcutaneous use
Sheep, goats: subcutaneous use
Pigs: intramuscular use

7. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle:
i.v.:
Meat and offal: 5 days.
Milk: 3 days.
s.c.:
Meat and offal: 12 days.
Milk: 4 days.

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 24745/3004
Vm 24745/5004

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Label vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrotron 100 mg/ml Solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance
Enrofloxacin 100 mg

3. TARGET SPECIES

Cattle, Sheep, Goats, Pigs

4. ROUTES OF ADMINISTRATION

Cattle: **i.v.** or **s.c.** use
Sheep, goats: **s.c.** use
Pigs: **i.m.** use

5. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle:
i.v.:
Meat and offal: 5 days.
Milk: 3 days.
s.c.:
Meat and offal: 12 days.
Milk: 4 days.

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/yy}
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 100 mg/ml Solution for injection for cattle, sheep, goats and pigs

2. Composition

Each ml contains:

Active substance:
Enrofloxacin 100 mg

Excipients:
1-Butanol 30.0 mg

Clear, slightly yellowish to yellowish orange solution.

3. Target species

Cattle, Sheep, Goats, Pigs

4. Indications for use

Cattle
Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mannheimia haemolytica* and *Mycoplasma* spp.
Treatment of acute severe mastitis caused by enrofloxacin susceptible strains of *Escherichia coli*.
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 in cattle less than 2 years old.

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 urinary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of post-partum dysgalactiae syndrome, PDS (MMA syndrome) caused by enrofloxacin susceptible strains of *Escherichia coli* and *Klebsiella* 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*.

5. Contraindications
Do not use for prophylaxis.
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:
The safety of the veterinary medicinal product has not been established in pigs or calves when administered by the intravenous route and use of this route of administration is not recommended in these animal groups.
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.
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 injection occurs seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
Cattle:
The safety of the veterinary medicinal product has been established in pregnant cows during the 1st quarter of pregnancy. The veterinary medicinal product can be used in pregnant cows during the 1st quarter of pregnancy.
The use of the veterinary medicinal product in cows during the 3 last quarters of pregnancy should be based on a benefit-risk assessment by the responsible veterinarian.
The veterinary medicinal product can be used in cows during lactation.

Sheep and Goats:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit-risk assessment by the responsible veterinarian.

Pigs:
The safety of the veterinary medicinal product has not been established during pregnancy. Use only according to the benefit-risk assessment by the responsible veterinarian.
The veterinary medicinal product can be used in sows during lactation.

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.

Overdose:
Do not exceed the recommended dosage. In accidental overdose there is no antidote and treatment should be symptomatic.
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, sheep, goats, pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Shock[1]
Digestive tract disorder (e.g. Diarrhoea)[2]

Undetermined frequency, (cannot be estimated from the available data):
Injection site inflammation[3]

[1] In cattle after intravenous administration, presumably as a result of circulatory impairment.
[2] Generally mild and transient.
[3] In pigs, after intramuscular administration, may persist up to 28 days after the injection.

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
5 mg of enrofloxacin/kg body weight (bw), corresponding to 1 ml/20 kg bw, once daily for 3-5 days.
Acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis* in cattle less than 2 years old: 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, once daily for 5 days.
The veterinary medicinal product can be administered by slow intravenous or subcutaneous administration.
Acute mastitis caused by *Escherichia coli*: 5 mg enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, by slow intravenous injection once daily for two consecutive days.
The second dose may be administered by the subcutaneous route. In this case, the withdrawal period following subcutaneous injection applies.
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/20 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/20 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 1.0 ml/20 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.

The stopper may be safely punctured up to 125 times. For multiple vial entry, an aspirating needle or multi-dose syringe is recommended to avoid excessive broaching of the stopper.

9. Advice on correct administration

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

10. Withdrawal periods

Cattle:
Following intravenous injection: Meat and offal: 5 days.
Milk: 3 days.

Following subcutaneous injection: Meat and offal: 12 days.
Milk: 4 days.

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 24745/3004
Vm 24745/5004

Pack sizes:
1 x 100 ml
12 x 100 ml
1 x 250 ml
12 x 250 ml

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