A. LABELLING

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>
<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>

Label/Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active Substance
Enrofloxacin 50.0 mg

Excipients
1-Butanol

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

1 x 100 ml, 12 x 100 ml

5. TARGET SPECIES

Cattle (calves)
Sheep
Goats
Pigs
Dogs
Cats

6. INDICATIONS

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:

Calves:
Intravenous use: Meat and offal: 5 days.
Subcutaneous use: 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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use by…..
Shelf-life after first opening the immediate packaging: 28 days

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read the package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

aniMedica GmbH
Im Südfeld 9
48308 Senden
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 24745/4030

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active Substance
Enrofloxacin 50.0 mg

Excipients
1-Butanol 30.0 mg

Clear, slightly yellowish to yellowish orange solution.

4. INDICATIONS

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 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 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 known hypersensitivity to fluoroquinolones or to any of the excipients.
Do not use when resistance / cross resistance to (fluoro)quinolones is known to occur.
Refer to section 12.
Do not use in growing horses because of possible deleterious damage on articular cartilage.

6. ADVERSE REACTIONS

Digestive tract disorders (e.g. diarrhoea) may occur in very rare cases. These signs are generally mild and transient.

Local reactions at injection site
In calves, transient local tissue reactions may occur in very rare cases and may be observed up to 14 days.
In pigs, after intramuscular administration of the product, inflammatory reactions may occur. They may persist up to 28 days after the injection.
In dogs, a moderate and transient local reaction (such as oedema) may occur.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

Alternatively, you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle (calves)
Sheep
Goats
Pigs
Dogs
Cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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

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 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 to avoid underdosing.

10. WITHDRAWAL PERIOD

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.
When the container is broached (opened) for the first time, using the in-use shelf life which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

Special precautions for use in animals
Official and local antimicrobial policies should be taken into account when the 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 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 toanimals
The 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 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.

Use during pregnancy or 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 (symptoms, emergency procedures, antidotes), if necessary
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 product at five times the recommended therapeutic dose.
In cattle, sheep and goats, overdose has not been documented.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused product or waste material should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2022

15. OTHER INFORMATION

100 ml clear glass vial type I with Teflon coated rubber stopper sealed with an aluminium cap.
Cartons of 1 x 100 ml or 12 x 100 ml are available.

Not all pack sizes may be marketed.
For animal treatment only - to be supplied only on veterinary prescription.

Approved 05 October 2022