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

Label/Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrotron 25 mg/ml Solution for injection for dogs, cats, rodents, reptiles and ornamental birds
Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Active Substance
Enrofloxacin 25.0 mg
Excipients
1-Butanol

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

1 x 50 ml, 12 x 50ml

5. TARGET SPECIES

Dogs
Cats
Rodents
Reptiles
Ornamental birds

6. INDICATIONS

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Do not use in birds intended for human consumption.

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-Bösensell
Germany

16. MARKETING AUTHORISATION NUMBER

Vm 24745/4029

17. MANUFACTURER'S BATCH NUMBER

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

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Enrotron 25 mg/ml Solution for injection for dogs, cats, rodents, reptiles and ornamental birds

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-Bösensell
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 25 mg/ml solution for injection for dogs, cats, rodents, reptiles and ornamental birds
Enrofloxacin

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

Each ml contains:

Active Substance	
Enrofloxacin	25.0 mg
Excipients	
1-Butanol	30.0 mg

Clear, slightly yellowish to yellowish orange solution.

4. INDICATIONS

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: *Staphylococcus* spp*., Escherichia coli, Pasteurella* spp*., Klebsiella* spp*., Bordetella* spp*., Pseudomonas* spp*. and Proteus* spp*.*

Rodents, reptiles and ornamental birds
Treatment of infections of the alimentary and respiratory tracts where clinical experience, if possible, supported by susceptibility testing of the causal organism, indicates enrofloxacin as the substance of choice.

5. CONTRAINDICATIONS

Do not use in dogs less than 1 year of age or in exceptionally large breeds of dog with a longer growth period under 18 months of age.
Do not use for cats less than 8 weeks of age.
Do not use in cases of known hypersensitivity to fluoroquinolones or to any of the excipients.
Do not use in animals that are epileptic or suffer from seizures since enrofloxacin may cause CNS stimulation.
Do not use for prophylaxis.
Do not use when resistance / cross resistance to (fluoro)quinolones is known to occur. Refer to section 12.

6. ADVERSE REACTIONS

In dogs enrofloxacin may affect articular cartilage during the period of rapid growth. Occasionally skin reactions have been seen after administration to kennelled greyhounds.

Local tissue reactions may occasionally occur at the injection site. Normal sterile precautions should be taken.

Rodents, reptiles and ornamental birds: Muscle bruising after injection in reptiles and birds has been reported occasionally.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs
Cats
Rodents
Reptiles
Ornamental birds

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

Subcutaneous or intramuscular use.
Repeated injections should be made at different injection sites.

Dogs and cats
5 mg of enrofloxacin/kg bw, corresponding to 1 ml/5 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 product information of the tablet product.

Rodents
10 mg/kg bw, corresponding to 0.4 ml/kg bw, once daily by subcutaneous injection for 5 to 10 consecutive days. If necessary, depending on the severity of clinical signs, this dosage can be doubled.

Reptiles
Reptiles are ectothermic, relying on external heat sources to maintain their body temperature at the optimum level for correct function of all body systems. Metabolism of substances and activity of the immune system are, thus, critically dependent on the body temperature. Therefore, the veterinarian must be aware of the correct temperature requirements of the respective reptile species and the hydration status of the individual patient. Furthermore, it has to be considered that large differences exist in the pharmacokinetic behaviour of enrofloxacin among different species, which additionally will influence the decision about the correct dosage of Enrotron 25 mg/ml Solution for injection.
Therefore, the recommendations made here can only be used as a starting point for individual dose setting.
5–10 mg/kg bw, corresponding to 0.2–0.4 ml/kg bw, once daily by intramuscular injection for 5 consecutive days.
An extension of the treatment interval to 48 hours may be necessary in individual cases. In complicated infections, higher dosages and longer treatment courses may be necessary. The presence of the renal portal system in reptiles means it is prudent to administer substances in the front half of the body wherever possible.

Ornamental birds
20 mg/kg bw, corresponding to 0.8 ml/kg bw, once daily by intramuscular injection for 5 to 10 consecutive days. In case of complicated infections higher doses may be necessary.

The use of a 0.5 ml (100 unit) insulin syringe should be considered for administration of the small volumes required by some species of small animals (mice, gerbils etc.)
Treatment may be initiated with the injection and maintained with an enrofloxacin containing oral solution.

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

Do not use in birds intended for human consumption.

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 the carton and the 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
The 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 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, lactation or lay
Do not use during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Antagonistic effects due to concurrent administration of macrolides and tetracyclines 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 dose. 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.

Dogs: 10-fold over dosage results in neurological symptoms such as ataxia, tremor, nystagmus or convulsions. These symptoms are reversible on cessation of treatment.

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

15. OTHER INFORMATION

50 ml clear glass vial type I with Teflon coated rubber stopper sealed with an aluminium cap.
Cartons of 1 x 50 ml or 12 x 50 ml are available.
Not all pack sizes may be marketed.
For animal treatment only - to be supplied only on veterinary prescription.

Approved: 22 February 2019