LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX 8.5 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrocat flavour 25 mg/ml oral suspension for cats [AT, BG, CZ, DE, DK, EL, ES, HU, IE, IS, IT, LT, LV, PL, PT, RO, SI, UK]
Enrocat flavour, 25 mg/ml oral suspension for cats [EE]
Enrocat vet 25 mg/ml oral suspension for cats [FI]
Enrofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

Enrofloxacin, 25 mg/ml

3. PHARMACEUTICAL FORM

Oral suspension.

4. PACKAGE SIZE

8.5 ml

5. TARGET SPECIES

Cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP
Shelf life after first opening the immediate packaging: 1 month
Use by: __/__/____

11. SPECIAL STORAGE CONDITIONS

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

Disposal: read 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

LIVISTO Int'l, S.L.
Av. Universitat Autònoma, 29
08290 Cerdanyola del Vallès (Barcelona)
Spain

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL 8.5 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrocat flavour 25 mg/ml oral suspension for cats [AT, BG, CZ, DE, DK, EL, ES, HU, IE, IS, IT, LT, LV, PL, PT, RO, SI, UK]
Enrocat flavour, 25 mg/ml oral suspension for cats [EE]
Enrocat vet 25 mg/ml oral suspension for cats [FI]
Enrofloxacin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Enrofloxacin, 25 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

8.5 ml

4. ROUTE(S) OF ADMINISTRATION

Oral use

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Enrocat flavour 25 mg/ml oral suspension for cats [AT, BG, CZ, DE, DK, EL, ES, HU, IE, IS, IT, LT, LV, PL, PT, RO, SI, UK]
Enrocat flavour, 25 mg/ml oral suspension for cats [EE]
Enrocat vet 25 mg/ml oral suspension for cats [FI]

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

Marketing authorisation holder:
LIVISTO Int'l, S.L.
Av. Universitat Autònoma, 29
08290 Cerdanyola del Vallès
(Barcelona), Spain

Manufacturer responsible for batch release:
Labiana Life Sciences, S.A.
Venus 26
08228 Terrassa
(Barcelona), Spain

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

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell Germany

aniMedica Herstellungs GmbH
Im Südfeld 9
48308 Senden-Bösensell Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrocat flavour 25 mg/ml oral suspension for cats
Enrofloxacin

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

Each ml contains:

Active substance:
Enrofloxacin…… 25 mg

Excipients:
Sorbic acid (E200)…… 1 mg

White to pale yellow suspension.

4. INDICATION(S)

For the treatment of single or mixed bacterial infections of the respiratory, digestive and urinary tract, otitis externa, skin and wound infections caused by the following enrofloxacin-sensitive Gram-positive and Gram-negative bacteria: *Staphylococcus* spp., *Escherichia coli*, *Haemophilus* spp. and *Pasteurella* spp.

5. CONTRAINDICATIONS

Do not use in animals with existing impairment of cartilage growth.
Do not use in animals with a known history of seizures, since enrofloxacin may cause CNS stimulation.
Do not use in animals with known hypersensitivity to fluoroquinolones or any of the excipients.
Do not use in animals less than 8 weeks of age.

6. ADVERSE REACTIONS

On very rare occasions, mild and transient gastrointestinal disorders, such as hypersalivation, vomiting or diarrhoea, may be observed. As a result, anorexia may occur.
Hypersensitivity reactions can occur.
In very rare cases, neurological signs (seizures, tremors, ataxia, excitation) and anaphylactic reactions can also 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}.

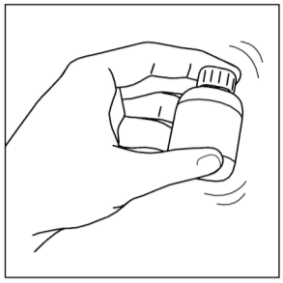
7. TARGET SPECIES

Cats

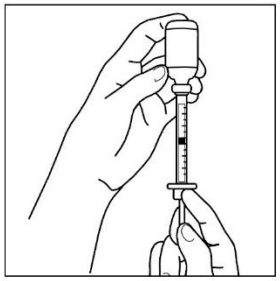
8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Oral use.
The product should be administered directly onto the back of the tongue and not in the animal's feed.
The dosage is 5 mg enrofloxacin per kg bodyweight once daily for 5 consecutive days. This is equivalent to 0.2 ml of the veterinary medicinal product per kg bodyweight once daily for 5 consecutive days.
In chronic and severe diseases, the duration of treatment can be extended up to 10 days. Treatment should be reconsidered if no improvement of the condition is observed after 3 days of treatment.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid over- or underdosing.
Do not exceed the recommended dosage.

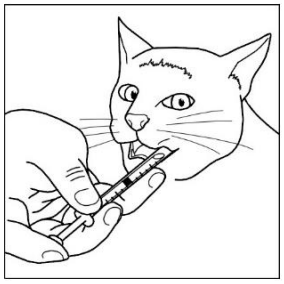
9. ADVICE ON CORRECT ADMINISTRATION



Shake well for 15 seconds before use



Draw out the appropriate dosage into the syringe



Administer directly onto the back of the tongue

In order to avoid cross-contamination, the same syringe should not be used for different animals. Thus, one syringe should only be used for one animal. After administration the syringe should be cleaned with tap water and stored in the carton box together with the product.
A 3 ml syringe with 0.1 ml graduations is supplied with every package of the product.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.
The expiry date refers to the last day of that month.
Shelf life after first opening the container: 1 month

12. SPECIAL WARNING(S)

Special warnings for each target species:
None.

Special precautions for use in animals:
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 instructions given in the SPC may increase the prevalence of bacteria resistant to fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.
Official and local antimicrobial policies should be taken into account when the product is used.
In cases of pyoderma, possible underlying primary disease should be identified and treated.
Enrofloxacin is partially excreted via the kidneys; as with all fluoroquinolones, excretion may therefore be delayed in individuals with existing renal damage. The product should be used with caution in animals with severe renal or hepatic impairment.
Retinotoxic effects including blindness can occur when the recommended dose is exceeded.

Do not use in cases of known resistance to quinolones or fluoroquinolones because of near-total cross-resistance to the former and complete cross-resistance to the latter.

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

- Enrofloxacin and sorbic acid may cause hypersensitivity (allergic reactions). People with known hypersensitivity to enrofloxacin or to any of the excipients should avoid contact with the veterinary medicinal product.
- The veterinary medicinal product may be irritant to skin and eyes.
- Avoid dermal and eye contact with the product. In case of accidental dermal and/or eye contact, wash any splashes from skin or eyes immediately with water.
- Do not eat, drink or smoke while handling the product.
- Enrofloxacin may cause gastrointestinal effects such as abdominal pain and diarrhoea if ingested. To avoid accidental ingestion, particularly by a child, do not leave a syringe containing the solution in the sight or reach of children. The used syringe should be stored with the product in the original carton. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
- Wash hands after use.

Pregnancy and lactation:

Laboratory studies in rats and chinchillas have not produced any evidence of a teratogenic, foetotoxic or, maternotoxic effects. As the safety has not been assessed in pregnant cats and enrofloxacin passes into the maternal milk, the use is not recommended during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

Combination of the product (enrofloxacin) with chloramphenicol, macrolide antibiotics or tetracyclines may produce antagonistic effects.

The concomitant administration of substances containing magnesium or aluminium may reduce the absorption of enrofloxacin. These drugs should be administered two hours apart.

Concomitant administration of theophylline requires careful monitoring as serum levels of theophylline may increase.

The concomitant use with digoxin should be avoided as fluoroquinolones can increase the bioavailability of digoxin.

Concurrent administration of fluoroquinolones may increase the action of oral anticoagulants.

Concomitant administration of fluoroquinolones in combination with non-steroidal anti-inflammatory drugs (NSAID) in animals could lead to seizures because of potential pharmacodynamic interactions in the CNS.

In animals subjected to rehydration, avoid excessive alkalinity of the urine.

Overdose (symptoms, emergency procedures, antidotes):

Do not exceed the recommended dosage. In the event of overdosing digestive tract disorders (vomiting, diarrhoea or hypersalivation) or CNS alterations (mydriasis, ataxia) may occur. In severe cases it may be necessary to interrupt the treatment.

Cats have been shown to suffer ocular damage after receiving doses higher than recommended. At doses of 20 mg/kg bw/day or higher, the toxic effects on the retina could lead to irreversible blindness in the cat.

To reduce the absorption of enrofloxacin taken orally the administration of antacids containing magnesium or aluminium is recommended.

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

<DD/MM/YYYY>

15. OTHER INFORMATION

Package size:
Cardboard box of 1 bottle of 8.5ml and a 3 ml oral syringe