Revised: April 2016
AN: 01395/2014

LABELLING AND PACKAGE LEAFLET

A. LABELLING

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

Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrotron Flavour 50 mg Tablets for dogs
Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 tablet contains:

Active substance:
Enrofloxacin……50.0 mg

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

10
20
30
50
100

5. TARGET SPECIES

Dogs

6. INDICATIONS

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

Shelf-life of divided tablets: 72 hours.
EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from light.
Divided tablets should be returned to the original package and used within 72 hours.
Do not store above 25°C.

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

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Distributor:
Where applicable

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

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

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrotron Flavour 50 mg Tablets for dogs
Enrofloxacin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

aniMedica GmbH
Germany

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

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

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

Revised: April 2016
AN: 01395/2014

PACKAGE LEAFLET FOR:
Enrotron Flavour 50 mg Tablets for dogs

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

Marketing authorisation holder and manufacturer responsible for batch release:
aniMedica GmbH
Im Südfeld 9
48308 Senden
Germany

Distributor:
where applicable

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrotron Flavour 50 mg Tablets for dogs
Enrofloxacin

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

Each tablet contains:

Active substance:
Enrofloxacin 50.0 mg

White to off-white, round tablet with one breakline and one decorative line. The tablet can be divided into two equal parts.

4. INDICATIONS

For the treatment of bacterial single or combined infections of the respiratory, alimentary or urinary tract, the skin or wounds, caused by Enrofloxacin-sensitive gram-negative and gram –positive bacteria*: E. coli, Pasteurella spp., Haemophilus spp*. and staphylococci.

5. CONTRAINDICATIONS

Do not use in young or growing dogs (dogs aged less than 12 months (small breed) or less than 18 months (large breed)) as the product may cause epiphyseal cartilage alterations in growing puppies.
Do not use in dogs having seizure disorders, since enrofloxacin may cause CNS stimulation.
Do not use in dogs with known hypersensitivity to fluoroquinolones or to any of the excipients of the product.
Do not use in case of resistance to quinolones, as there exists almost complete cross resistance to other quinolones and complete cross resistance to other fluoroquinolones.
Do not use with tetracyclines, phenicols or macrolides because of potential antagonistic effects.
See also section 12. “Special Warnings”.

6. ADVERSE REACTIONS

In rare cases vomiting and diarrhoea are observed.
See section 5. “Contraindications”

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports)

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

7. TARGET SPECIES

Dogs.

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

Tablet for oral use.

Dose: 5 mg enrofloxacin per kg body weight (BW) daily, corresponding to:
½ tablet for 5 kg body weight
1 tablet per 10 kg body weight.

Can be administered directly or given with food.
Treatment generally takes place over 5 - 10 consecutive days.
If there is no clinical improvement within 3 days, the sensitivity test is to be repeated and it may be necessary to switch to a different treatment.

The recommended doses should not be exceeded.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD

Not applicable.

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 label.
The expiry date refers to the last day of that month.
Store in the original package in order to protect from light.
Divided tablets should be returned to the original package.
Shelf-life of divided tablets: 72 hours.
Do not store above 25°C.

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. Skin infections are mostly secondary to an underlying disease. It is advisable to determine the underlying cause and to treat the animal accordingly.
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 fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential cross resistance. As enrofloxacin is metabolized by the liver and partly eliminated via the kidneys, elimination may be delayed in dogs with liver or renal disturbances. Therefore, in cases of known liver or renal impairment, the product should be used with caution.
The chewable tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
People with known hypersensitivity to fluoroquinolones should avoid contact with the veterinary medicinal product.
Wash hands after use.
In case of contact with the eyes, wash immediately with plenty of clean water.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Use during pregnancy, lactation or lay
Pregnancy:
Do not use during pregnancy.

Lactation:
Do not use during lactation.

Interaction with other medicinal products and other forms of interaction
Concurrent use of flunixin should be under careful veterinary monitoring, as the interactions between these drugs may lead to adverse events related to delayed elimination.
Elimination of theophylline may be delayed.
Antagonistic effect may occur if enrofloxacin is combined with phenicols, macrolide antibiotics or tetracyclines.
Substances containing magnesium or aluminium, if administered at the same time, may impair the enrofloxacin resorption.

Overdose (symptoms, emergency procedures, antidotes), if necessary
Overdosing can cause vomiting and nervous signs (muscle tremor, incoordination and convulsions) which may require treatment discontinuation.
In the absence of any known antidote, apply drug elimination methods and symptomatic treatment.
If necessary, administration of aluminium- or magnesium-containing antacids or activated carbon can be used to reduce absorption of enrofloxacin.
According to literature, signs of overdose with enrofloxacin in dogs such as inappetence and gastrointestinal disturbance were observed at approximately 10 times the recommended dose when administered for two weeks. No signs of intolerance were observed in dogs administered 5 times the recommended dose for a month.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

10, 20, 30, 50, 100 tablets packed in blisters of 10 tablets consisting either of PVC / Aluminium foils or Aluminium / Aluminium foils
Cardboard box containing 1, 2, 3, 5, 10 blisters.
Not all pack sizes may be marketed.
For animal treatment only - to be supplied only on veterinary prescription.

[To be completed nationally, if different to MAH.]