Revised: May 2016
AN: 00881/2015

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**
**Card box (for PE bottle 8.5 ml or 15 ml)**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril flavour 25 mg/ml oral suspension for cat
(all MS except, DK, FI, IS, NO, SE and ES)
(The product name will be translated into national languages)
Baytril Sabor 25 mg/ml suspensión oral para gatos (ES)

Lorenax vet. 25 mg/ml oral suspension for cat **(**DK),
Baytril vet. 25 mg/ml oral suspension for cat (FI, IS, NO and SE)

enrofloxacin

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml of the product contains:

**Active substance**:

Enrofloxacin 25 mg

**Excipient(s):**

Ascorbic acid (E300) 0.2 mg
Sorbic acid (E200) 2 mg

## 3. PHARMACEUTICAL FORM

Oral suspension

## 4. PACKAGE SIZE

8.5 ml
15 ml

## 5. TARGET SPECIES

Cat

## 6. INDICATION(S)

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.
Shake well before use.

Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD

## 9. SPECIAL WARNING(S), IF NECESSARY

The product should not be administered in the animal`s feed.

## 10. EXPIRY DATE

EXP {month/year}
Once broached, use within 3 months.

## 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

{Name and address}
<{Tel.}>
<{Fax}>
<{E-mail}>

## 16. MARKETING AUTHORISATION NUMBER(S)

XXXXX

## 17. MANUFACTURER'S BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Polyethylene bottle (Content 8.5 ml, 15 ml)**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril flavour 25 mg/ml oral suspension for cat

enrofloxacin

## 2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

8.5 ml
15 ml

## 4. ROUTE(S) OF ADMINISTRATION

Oral use. Shake well before use.

## 5. WITHDRAWAL PERIOD

## 6. BATCH NUMBER

Lot {number}

## 7. EXPIRY DATE

EXP {month/year}
Once opened use by…

## 8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

# B. PACKAGE LEAFLET

**PACKAGE LEAFLET FOR:**
**Baytril flavour 25 mg/ml oral suspension for cat**

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

Marketing authorisation holder:
National Bayer Animal Health subsidiary:

Manufacturer responsible for batch release:
KVP Pharma + VeterinärProdukte GmbH
Projensdorfer Str. 324
24106 Kiel
Germany

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril flavour 25 mg/ml oral suspension for cat (all MS except, DK, FI, IS, NO, SE and ES)
(The product name will be translated into national languages)
Baytril Sabor 25 mg/ml suspensión oral para gatos (ES)

Lorenax vet. 25 mg/ml oral suspension for cat (DK),
Baytril vet. 25 mg/ml oral suspension for cat (FI, IS, NO and SE)

Enrofloxacin

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

1 ml white to yellow-white suspension contains:
**Active substance**
Enrofloxacin 25 mg

**Excipients:**
Ascorbic acid (E300) 0.2 mg
Sorbic acid (E200) 2.0 mg

## 4. INDICATION(S)

For the treatment of single or mixed bacterial infections of the respiratory, alimentary and urinary tract, skin or wounds caused by the following enrofloxacin-sensitive Gram-negative and Gram-positive bacteria:
Staphylococci, *E. coli, Haemophilus* spp. and *Pasteurella* spp.

## 5. CONTRAINDICATIONS

Do not use in

- Animals with existing impairment of cartilage growth
- Animals with a known history of seizures, since enrofloxacin may cause CNS stimulation.
- Animals with known hypersensitivity to fluoroquinolones or any of the excipients.

For use in pregnant animals and for interactions with other medicinal products see section special warnings.

## 6. ADVERSE REACTIONS

In rare cases mild digestive tract disorders e.g. anorexia, vomiting or diarrhoea may occur. This effect usually disappears spontaneously and treatment normally does not have to be stopped. Hypersalivation may occur following administration of the product.

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

Cat

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

For oral use in cats.

The product should not be administered in the animal`s feed.
The dosage is 5 mg enrofloxacin per kg bodyweight (BW) once daily.

This is equivalent to 0.2 ml per kg bodyweight once daily.

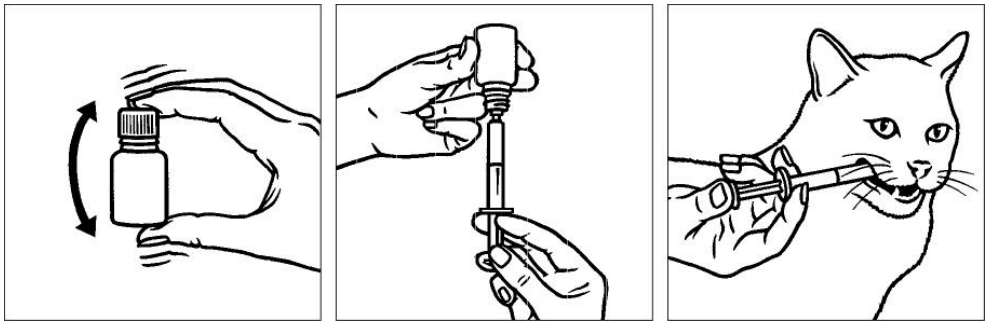
Treatment is generally given for 5 - 10 consecutive days.

Treatment should be reconsidered if no improvement of the condition is observed after 3 days of treatment.

To ensure a correct dosage bodyweight should be determined as accurately as possible to avoid over- or underdosing.

Do not exceed the recommended dosage.

Figure 1: Administration of the product



| | | |
|---|---|---|
| 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 8.5 ml and 15 ml package of the product.
For cats weighing less than 2 kg a commercially available 1 ml single dose fine dosage syringe with 0.01 ml graduations should be used.

## 9. ADVICE ON CORRECT ADMINISTRATION

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.

## 10. WITHDRAWAL PERIOD

Not applicable.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not use this medicinal product after the expiry date stated on the bottle after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the container: use within 3 months.

## 12. SPECIAL WARNING(S)

Special warnings
Do not use in cases of known resistance to quinolones because of near-total cross-resistance with these compounds and complete cross-resistance with other fluoroquinolones.

In animals where product administration is associated with excessive salivation or where difficulty administering the required dose is experienced, administration should be discontinued and an alternative therapy used.

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.

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 irreversible blindness can occur in cats when the recommended dose is exceeded.
The safety of enrofloxacin in kittens weighing less than 0.5 kg or under 8 weeks of age has not been established.

See also section contraindications

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental ingestion, seek medical advice immediately and show the package leaflet to the physician.
Wash hands after use.
Wash any splashes from skin or eyes immediately with water.
Do not eat, drink or smoke while handling the product.
People with known hypersensitivity to fluoroquinolones should avoid contact with the veterinary medical product

Pregnancy:
Studies in laboratory animals (rat, chinchilla) have not produced any evidence of a teratogenic, foetotoxic, maternototoxic effect. As the safety has not been assessed in pregnant queens, use only according to the benefit/risk assessment by the responsible veterinarian.

Lactation:
As enrofloxacin passes into the maternal milk, the use is not recommended during 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.

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

Overdose (symptoms, emergency procedures, antidotes):
In the event of extensive overdosing the first symptoms to be expected are loss of appetite and vomiting. To reduce the absorption of enrofloxacin taken orally the administration of antacids containing magnesium or aluminium is recommended.

In very rare cases diarrhoea or CNS symptoms (muscle tremor, incoordination and convulsions) may occur after administration of the product which may require treatment discontinuation.

Retinotoxic effects including irreversible blindness can occur in cats when the recommended dose is exceeded by 2-4 times and above.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.
These measures should help to protect the environment.

Medicines should not be disposed of via wastewater or household waste.

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

## 15. OTHER INFORMATION

Package size:
8.5 ml package: high density polyethylene bottle with a polyethylene insert, a child resistant closure and a 3 ml polypropylene oral dosing syringe with 0.1 ml graduations

15 ml package: high density polyethylene bottle with a polyethylene insert, a child resistant closure and a 3 ml polypropylene oral dosing syringe with 0.1 ml graduations

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved: 26 May 2016