ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril flavour 25 mg/ml oral suspension for cat

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Enrofloxacin 25 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Ascorbic acid (E300)	0.2 mg
Sorbic acid (E200)	2 mg
Polacrilin	
Dispersible cellulose (Microcrystalline cellulose and Carmellose Sodium)	
Propylene glycol (E1520)	
Vanilla flavour	
Purified water	

White to yellow-white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each target species

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

3.3 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 cases of hypersensitivity to the active substance, to other fluoroquinolones or to any of the excipients.

3.4 Special warnings

Cross-resistance has been shown between fluoroquinolones in *Escherichia coli* and other target pathogens. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to fluoroquinolones because its effectiveness may be reduced.

In animals where the veterinary medicinal 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach. Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Enrofloxacin is partially excreted via the kidneys; as with all fluoroquinolones, excretion may therefore be delayed in individuals with existing renal damage.

The veterinary medicinal 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 3.3 for 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 or the label 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 veterinary medicinal product.
People with known hypersensitivity to fluoroquinolones should avoid contact with the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cats:

Rare (1 to 10 animals / 10 000 animals treated):	Digestive tract disorder (e.g. Diarrhoea[1], Vomiting[1] Anorexia[1])
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Hypersalivation

[1] Mild. Disappears spontaneously, and treatment normally does not have to be stopped.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Laboratory studies in rats and chinchillas have not produced any evidence of teratogenic, foetotoxic, maternotoxic effects.
The safety of the veterinary medicinal product has not been established during pregnancy in 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.

3.8 Interaction with other medicinal products and other forms of interaction

Combination of the veterinary medicinal 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) in animals could lead to seizures because of potential pharmacodynamic interactions in the CNS.

3.9 Administration routes and dosage

Oral use.
The veterinary medicinal 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.

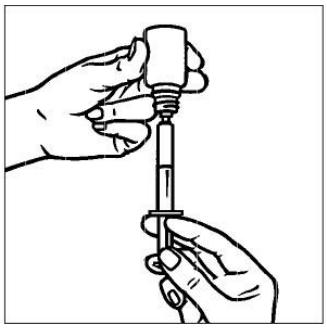
Treatment should be reconsidered if no improvement of the condition is observed after 3 days of treatment.

To ensure a correct dosage body weight should be determined as accurately as possible.

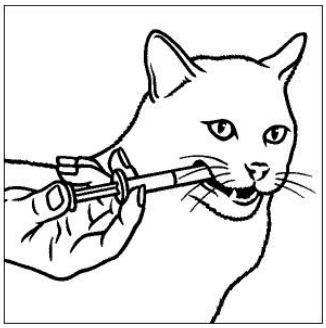
Do not exceed the recommended dosage.

Figure 1: Administration of the veterinary medicinal 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 veterinary medicinal product.

A 3 ml syringe with 0.1 ml graduations is supplied with every 8.5 ml and 15 ml package of the veterinary medicinal 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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 veterinary medicinal 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01MA90.

4.2 Pharmacodynamics

Enrofloxacin is a member of the fluoroquinolone class of chemical compounds. The substance has bactericidal activity, which is the result of its binding to the A-subunit of bacterial DNA gyrase, thereby selectively inhibiting that enzyme.
DNA gyrase belongs to a class of enzymes known as topoisomerases, which are involved in the replication, transcription and recombination of bacterial DNA. Fluoroquinolones also control bacteria in the stationary phase by altering the permeability of the bacterial cell wall. Enrofloxacin exerts a concentration-dependent bactericidal action with similar values for minimal inhibitory concentration and minimal bactericidal concentrations.
Enrofloxacin has antimicrobial activity against the following enrofloxacin-sensitive Gram- negative and Gram-positive bacteria: Staphylococci, *E. coli, Haemophilus* spp. and *Pasteurella* spp..

Induction of resistance against quinolones can develop by mutations in the gyrase gene of bacteria and by changes in cell permeability towards quinolones. Both mechanisms result in decreased susceptibility of bacteria to fluoroquinolones.

Clinical breakpoints established by CLSI[1] in 2024 for enrofloxacin in cats for ear infections are as follows:

Organism	Minimum inhibitory concentration breakpoints of enrofloxacin (mcg/ml)		
	susceptible	intermediate	resistant
Staphylococcus intermedius	≤0.5	≤2	≥4
Staphylococcus felis	≤0.5	≤2	≥4
Escherichia coli	≤0.5	≤2	≥4

[1] CLSI. Performance standards for antimicrobial disk and dilution susceptibility tests for bacteria isolated from animals: 7th ed. CLSI supplement Vet01S Clinical and Laboratory Standards Institute.

Clinical breakpoints established by CLSI[1] in 2024 for enrofloxacin in cats for skin and soft tissue infections are as follows:

Organism	Minimum inhibitory concentration breakpoints of enrofloxacin (mcg/ml)		
	susceptible	intermediate	resistant
Staphylococcus aureus	≤0.5	≤2	≥4
Staphylococcus intermedius	≤0.5	≤2	≥4
Staphylococcus felis	≤0.5	≤2	≥4
Escherichia coli	≤0.5	≤2	≥4

[1] CLSI. Performance standards for antimicrobial disk and dilution susceptibility tests for bacteria isolated from animals: 7th ed. CLSI supplement Vet01S Clinical and Laboratory Standards Institute.

4.3 Pharmacokinetics

After administration of the veterinary medicinal product at a single oral dose of 5 mg enrofloxacin per kg body weight to cats, maximum serum levels of approximately 2.2 mcg/ml are reached within 1 hour.
Other studies with enrofloxacin showed an overall high oral availability of >80 %. A distribution volume of over 2 l/kg indicates good tissue penetration of enrofloxacin, with high concentrations being found in major organs, including the skin, urine, cerebrospinal fluid and bile. The tissue concentrations often exceed serum concentrations. In general fluoroquinolones tend to accumulate in macrophages and neutrophils. Protein binding in serum is 40 %. Enrofloxacin is partially metabolized to the active substance ciprofloxacin.
Both active substances are partially eliminated via the kidney. Terminal half-life of enrofloxacin is approximately 7 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate packaging: 3 months.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

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 in a cardboard box.

Pack sizes:
8.5 ml
15 ml

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

DD/MM/YYYY

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

MM/YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril flavour 25 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Enrofloxacin 25 mg/ml

3. PACKAGE SIZE

8.5 ml
15 ml

4. TARGET SPECIES

Cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.
Shake well before use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 3 months.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco logo

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril flavour

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Enrofloxacin 25 mg/ml

8.5 ml
15 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 3 months by: …

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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]
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]

2. Composition

Each ml contains:

Active substance:
Enrofloxacin 25 mg

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

White to yellow-white suspension.

3. Target species

Cats.

4. Indications for use

For the treatment of single or mixed bacterial infections of the respiratory, alimentary and urinary tract, skin or wounds caused by the following Gram-positive and Gram-negative bacteria: Staphylococci, *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 cases of hypersensitivity to the active substance, to other fluoroquinolones or to any of the excipients.

6. Special warnings

Special warnings:

Cross-resistance has been shown between fluoroquinolones in *Escherichia coli* and other target pathogens. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to fluoroquinolones because its effectiveness may be reduced.

In animals where the veterinary medicinal 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 safe use in the target species:

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach. Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Enrofloxacin is partially excreted via the kidneys; as with all fluoroquinolones, excretion may therefore be delayed in individuals with existing renal damage.

The veterinary medicinal 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 or the label 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 veterinary medicinal product.
People with known hypersensitivity to fluoroquinolones should avoid contact with the veterinary medicinal product.

Pregnancy:
Laboratory studies in rats and chinchillas have not produced any evidence of teratogenic, foetotoxic, maternotoxic effects.
The safety of the veterinary medicinal product has not been established during pregnancy in 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 veterinary medicinal 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) in animals could lead to seizures because of potential pharmacodynamic interactions in the CNS.

Overdose:

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 veterinary medicinal 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.

Major incompatibilities:

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

7. Adverse events

Cats:

Rare (1 to 10 animals / 10 000 animals treated):	Digestive tract disorder (e.g. Diarrhoea[1], Vomiting[1] Anorexia[1])
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Hypersalivation

[1] Mild. Disappears spontaneously, and treatment normally does not have to be stopped.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Oral use.
The veterinary medicinal product should not be administered in the animal's feed.

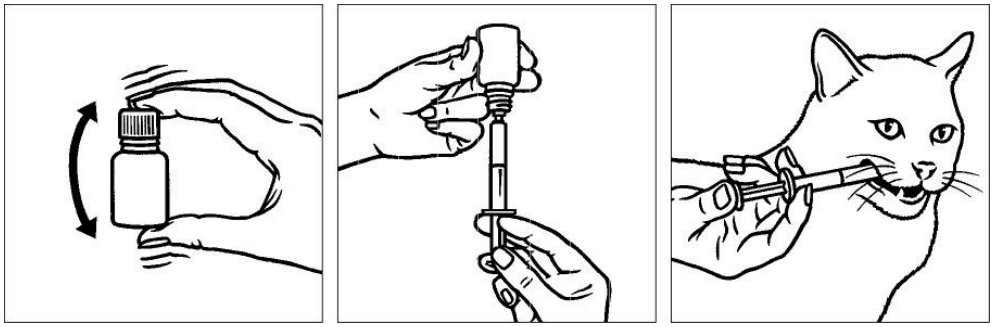
The dosage is 5 mg enrofloxacin per kg bodyweight (BW) once daily. This is equivalent to 0.2 ml per kg bodyweight once daily.
Treatment is generally given for 5-10 consecutive days.

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.
Do not exceed the recommended dosage.

9. Advice on correct administration

Figure 1: Administration of the veterinary medicinal 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 veterinary medicinal product.

A 3 ml syringe with 0.1 ml graduations is supplied with every 8.5 ml and 15 ml package of the veterinary medicinal 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.

10. Withdrawal periods

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 vial after Exp.
The expiry date refers to the last day of that month.

Shelf-life after first opening the immediate packaging: 3 months.

12. Special precautions for disposal

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Cardboard box with 1 x 8.5 ml or 15 ml bottle and an oral syringe.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

16. Contact details

Marketing authorisation holder <and contact details to report suspected adverse events>:

Manufacturer responsible for batch release:

KVP Pharma + Veterinär Produkte GmbH, Projensdorfer Str. 324, 24106 Kiel, Germany

<Local representatives< and contact details to report suspected adverse events>:>