PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril Flavour Tablets 150 mg

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains: Enrofloxacin 150 mg

3. PACKAGE SIZE

100 tablets.

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Store in a dry place.
Keep the blister in the outer carton.

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 GmbH

14. MARKETING AUTHORISATION NUMBER

Vm 52127/5138
Vm 52127/3063

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril Flavour Tablets 150 mg

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains: Enrofloxacin 150 mg

3. TARGET SPECIES

Dogs.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Store in a dry place.
Keep the blister in the outer carton.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Baytril Flavour Tablets 15 mg
Baytril Flavour Tablets 50 mg
Baytril Flavour Tablets 150 mg

2. Composition

Each tablet contains:

Active substance:

15 mg Tablets:	Enrofloxacin 15 mg
50 mg Tablets:	Enrofloxacin 50 mg
150 mg Tablets:	Enrofloxacin 150 mg

Excipients:

15 mg Tablets:	Artificial beef flavour Irradiated	6 mg
50 mg Tablets:	Artificial beef flavour Irradiated	12 mg
150 mg Tablets:	Artificial beef flavour Irradiated	42 mg

A light brown to brown, slightly marbled, round, planar tablet for oral administration to dogs and cats.

3. Target species

Cats and dogs

4. Indications for use

The veterinary medicinal product is for use in dogs and cats in the treatment of bacterial infections of the alimentary, respiratory and urogenital tracts, skin, secondary wound infections and otitis externa where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of the choice.

5. Contraindications

Not for 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, as articular cartilage may be affected during the period of rapid growth.
Not recommended for use in cats less than 8 weeks of age.

The veterinary medicinal product should not be used for prophylaxis.

6. Special warnings

Special warnings:
Please refer to section 'Contraindications'.
Cats: Retinotoxic effects including blindness can occur when the recommended dose is exceeded.

Special precautions for safe use in the target species:

Do not exceed the recommended dosage.
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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product should be used with caution in animals with severe renal or hepatic impairment. Retinotoxic effects including blindness can occur in cats when the recommended dose is exceeded.
Enrofloxacin-containing products should not be used in animals with persisting articular cartilage growth disorders, since disorders may worsen during treatment.

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 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. In case of contact with skin or eyes, wash the affected area with clear running water.
- Wash hands after use.

Special precautions for the protection of the environment:

Not applicable

Pregnancy and lactation:
The veterinary medicinal product may be used safely in pregnant and lactating animals.

Interaction with other medicinal products and other forms of interaction:
Do not use enrofloxacin concomitantly with antimicrobial substances acting antagonistically to quinolones (e.g. macrolides, tetracyclines, or phenicols).
Do not use concurrently with theophylline as the elimination of theophylline may be delayed.
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 coadministration 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 Cmax of enrofloxacin.
Concurrent oral applications of substances containing calcium, aluminium or magnesium hydroxide (e.g. antacids), or multivitamins containing iron or zinc can interfere with intestinal absorption of fluoroquinolones. Enrofloxacin should therefore not be used concomitantly with those products.
The combined use of fluoroquinolones with digoxin should also be avoided because of potentially increased oral bioavailability of digoxin.

Overdose:
Do not exceed the recommended dose. In accidental overdose, vomiting, diarrhoea and CNS/behavioural changes may occur. 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.

Major incompatibilities:
None known.

7. Adverse events

Dog

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Digestive tract disorders[1] (e.g. diarrhoea, hypersalivation, vomiting); Anorexia[2]; Anaphylactic-type reaction (severe allergic reaction); Neurological disorders (e.g. ataxia (incoordination), seizure, tremor, excitation); Joint cartilage disorder[3].

[1] Mild and transient.

[2] As a result of gastrointestinal disorders.

[3] During the period of rapid growth articular cartilage development may be affected.

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 using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

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

Oral use

Dogs and cats
The dose rate of enrofloxacin is 5 mg/kg given orally once daily or as a divided dose twice daily for 3 to 10 days with or without food. Treatment may be initiated with Baytril 5% Injection or Baytril 2.5% Injection and maintained with the tablets.

The daily dose is achieved as follows:

Cats and Small Dogs
Baytril Flavour Tablets 15 mg: 1 tablet per 3 kg bodyweight.
Medium Dogs
Baytril Flavour Tablets 50 mg: 1 tablet per 10 kg bodyweight.
Large Dogs
Baytril Flavour Tablets 150 mg: 1 tablet per 30 kg bodyweight

9. Advice on correct administration

10. Withdrawal periods

Not applicable

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25°C. Store in a dry place.
Do not use this veterinary medicinal product after the expiry date which is stated on

the label or carton after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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 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

Vm 52127/5137 & Vm 52127/3062 Baytril Flavour Tablets 15 mg

Vm 52127/5139 & Vm 52127/3064 Baytril Flavour Tablets 50 mg

Vm 52127/5138 & Vm 52127/3063 Baytril Flavour Tablets 150 mg

Strips of 10 tablets in blister foil supplied in dispensing cartons containing 100 tablets.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

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

Elanco GmbH
Heinz-Lohmann Strasse 4
Groden
27472 Cuxhaven
Germany
Tel: +44 3308221732
PV.GBR@elancoah.com
PV.XXI@elancoah.com

Manufacturer responsible for batch release:

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

17. Other information

POM-V

Approved 21 May 2026

Gavin Hall