1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril Flavour Tablets 150 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance: Enrofloxacin 150 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Lactose monohydrate	
Maize starch	
Microcrystalline cellulose	
Polyvidone/Povidone	
Magnesium stearate	
Silica colloidal anhydrous	
Artificial beef flavour Irradiated	42 mg

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

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

The veterinary medicinal product is for use in dogs 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.

3.3 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.

The veterinary medicinal product should not be used for prophylaxis.

3.4 Special warnings

Please refer to item 3.3.

3.5 Special precautions for use

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.

3.6 Adverse events

Dogs:

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; Neurological disorders (e.g. ataxia, 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing

authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

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

3.8 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 C_{max} 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.

3.9 Administration routes and dosage

Oral use.

The dosage 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 Baytril Flavour Tablets.

The daily dose is achieved as follows:
Large dogs: 1 Baytril Flavour Tablet 150 mg per 30 kg bodyweight.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

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

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01MA90

4.2 Pharmacodynamics

Enrofloxacin is bactericidal in action with activity against Gram positive and Gram negative bacteria and mycoplasmas. The mechanism of action of the quinolones is unique among antimicrobials - they act primarily to inhibit bacterial DNA gyrase, an enzyme responsible for controlling the supercoiling of bacterial DNA during replication. Resealing of the double standard helix is inhibited resulting in irreversible degradation of the chromosomal DNA. The fluoroquinolones also possess activity against bacteria in the stationary phase by an alteration of the permeability of the outer membrane phospholipid cell wall.

4.3 Pharmacokinetics

The pharmacokinetics of enrofloxacin in dogs and cats are such that oral and parenteral administration leads to similar serum levels. Enrofloxacin possesses a high distribution volume. Tissue levels 2-3 times higher than that found in the serum, have been demonstrated in laboratory animals and target species. Organs in which high levels can be expected are the lungs, liver, kidney, skin, bone and lymphatic system. Enrofloxacin also distributes into the cerebrospinal fluid, the aqueous humour and the foetus in pregnant animals.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.

5.3 Special precautions for storage

Do not store above 25 °C. Store in a dry place.

5.4 Nature and composition of immediate packaging

Container material:	Aluminium foil blister or plastic coated aluminium blister
Container colour:	Silver or white coloured
Container volume:	Strips of 10 light brown unmarked tablets supplied in dispensing cartons containing 100 tablets.

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

Elanco GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA22020/065/003

8. DATE OF FIRST AUTHORISATION

01/10/1988

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

19/06/2025

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).