Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril Flavour Tablets 50 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Constituents	mg/tablet
Enrofloxacin	50.0

Relevant constituents of the Excipient	
Artificial beef flavour Irradiated	12.0

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Tablet.
Light brown to brown, slightly marbled, round, curved, scored tablets for oral administration to dogs

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the target species

The 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.

4.3 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.
Baytril Flavour Tablets 50 mg should not be used for prophylaxis.

4.4 Special warnings for each target species

Please see point 4.3.

4.5 Special precautions for use

Special precautions for use in animals
Do not exceed the recommended dose.
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. 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 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.

4.6 Adverse reactions (frequency and seriousness)

On very rare occasions, mild and transient gastrointestinal disorders, such as hypersalivation, vomiting or diarrhoea, may be observed. As a result, anorexia may occur.

In very rare cases, neurological signs (seizures, tremors, ataxia, excitation) and anaphylactic reactions can also occur.

During period of rapid growth enrofloxacin may affect articular cartilage development.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interactions

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.

4.9 Amounts to be administered and administration route

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:

Medium dogs: 1 Baytril Flavour Tablet 50 mg per 10 kg bodyweight

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Do not exceed the recommended dose. In accidental overdose vomiting, diarrhoea and CNS/behaviural changes may occur. There is no antidote and treatment should be symptomatic.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Enrofloxacin is a synthetic, broad spectrum antimicrobial substance, belonging to the fluoroquinoline group of antibiotics.
ATCVet Code: QJ01MA90

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

The pharmokinetics 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize Starch
Microcrystalline cellulose
Polyvidone/Povidone
Magnesium Stearate
Silica colloidal anhydrous
Artificial beef flavour Irradiated

6.2 Major incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

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

6.5 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.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann-Strasse 4
27472 Cuxhaven
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA22020/065/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1988
Date of last renewal: 30 September 2008

10 DATE OF REVISION OF THE TEXT

July 2023