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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
None.

4.6 Adverse reactions (frequency and seriousness)

In dogs enrofloxacin may affect articular cartilage during the period of rapid growth.

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

None known.

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 clloidal 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
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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

October 2020