SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril Flavour Tablets 15 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 Active Constituents	mg per tablet
Enrofloxacin	15.0

2.2 Relevant Constituents of the Excipients

Artificial beef flavour Irradiated	6.0

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and Cats.

4.2 Indications for use, specifying the target species

The 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 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.
Not recommended for use in cats less than 8 weeks of age.
Baytril Flavour Tablets 15 mg should not be used for prophylaxis.

4.4 Special warnings for each target species

Please refer to item 4.3.

Cats: Retinotoxic effects including blindness can occur when the recommended dose is exceeded.

4.5 Special precautions for use

i. Special precautions for use in animals

Do not exceed the recommended dosage

ii. Special precautions to be taken by the person administering the medicinal product to animals

None.

iii. Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

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

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 interaction

None known.

4.9 Amount(s) 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:-

Cats and small dogs: 1 Baytril Flavour Tablet 15 mg per 3 kg bodyweight.

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

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.

4.11 Withdrawal period(s)

Not applicable

5. PHARMACOLOGICAL PROPERTIES

Enrofloxacin is a synthetic, broad spectrum antimicrobial substance, belonging to the fluoroquinolone group of antibiotics.

ATC Vet Code: QJ01MA90

5.1 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.

5.2 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.

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 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 25ºC. 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 product or waste materials derived from the use of such products, if appropriate

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

7. MARKETING AUTHORISATION HOLDER

UK Only:	IE Only:
Elanco Europe Ltd. Form 2, Bartley Way Bartley Wood Business Park Hook RG27 9XA United Kingdom	Bayer Ltd, Animal Health Division, The Atrium, Blackthorn Road, Dublin 18, Ireland

8. MARKETING AUTHORISATION NUMBERS

UK Only:	IE Only:
Vm 00879/4120	VPA 10021/5/1

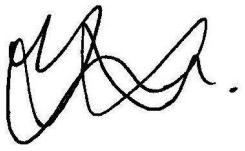
9. DATE OF FIRST AUTHORISATION

UK Only:	IE Only:
20 May 1992	01 October 1988

10. DATE OF REVISION OF THE TEXT

UK Only:

September 2020



Approved: 17 September 2020