SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril 25 mg/ml Oral Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substances: Enrofloxacin 25.0 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl Alcohol	14.0 mg
Potassium Hydroxide	
Hypromellose	
Water purified	

Clear, aqueous solution.

3. CLINICAL INFORMATION

3.1 Target species

Calves
Exotic Animals (small mammals, reptiles and avian species)

3.2 Indications for use for each target species

The product is for use in calves in the treatment of infections of the alimentary and respiratory tracts of bacterial or mycoplasmal origin (e.g. pasteurellosis, mycoplasmosis, coli-bacilliosis and salmonellosis), where clinical experience supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.
The product may also be used in exotic animals (small mammals, reptiles and avian species) for the treatment of bacterial infections of the alimentary and respiratory tracts where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

3.3 Contraindications

The product should not be used for prophylaxis.

3.4 Special warnings

Exotic Animals: Consult the Technical Services Department of Elanco prior to use.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Official and local antimicrobial policies should be taken into account when the product is used.
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 the instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.

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 should avoid contact with the veterinary medicinal product.
The veterinary medicinal product may be irritant to skin and eyes.
Personal protection equipment consisting of impervious gloves should be worn when handling the product.
Wash any splashes from skin or eyes immediately with water. Wash hands and exposed skin after use.
Do not eat, drink or smoke whilst using the product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Target Species: Cattle

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
In the absence of data on its use in some exotic species, caution should be used when prescribing during these periods and a careful risk/benefit assessment made.

Common (1 to 10 animals / 100 animals treated):	
Uncommon (1 to 10 animals / 1000 animals treated):	
Rare (1 to 10 animals / 10,000 animals treated):	
Very rare (< 1 animal / 10,000 animals treated, including isolated reports):	Gastrointestinal disorders (e.g. Diarrhoea, Vomiting) Joint cartilage disorder Anorexia

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). The simultaneous application of substances containing aluminium or magnesium can impair the absorption of enrofloxacin.

3.9 Administration routes and dosage

Oral use

Calves
Administer via the milk, milk replacer, electrolyte solution or water. The dose rate is 2.5 mg enrofloxacin per kg bodyweight (5 ml per 50 kg) daily for 3 days. This rate may be doubled to 5 mg per kg (10 ml per 50 kg) for 5 days for salmonellosis and complicated respiratory disease.
Medicated fluids should be made up immediately prior to provision on a daily basis.

Exotic Animals
The dose rates given below are for guidance only. Veterinary surgeons are advised to contact the company prior to use to discuss the particulars of each individual case.
Small Mammals
5 mg enrofloxacin per kg bodyweight (0.2 ml per kg bodyweight) orally diluted in water, twice daily for 7 days.

Reptiles
5 mg enrofloxacin per kg bodyweight (0.2 ml per kg bodyweight) orally diluted in water, at 24-48 hour intervals for 6 days.

Birds (excluding chickens and turkeys)
10 mg enrofloxacin per kg bodyweight (0.4 ml per kg bodyweight) orally diluted in water, twice daily 7 days.
For direct administration by gavage, dilutions of 1 part product to 4 parts water are recommended. If the product is to be given via the drinking water, concentrations of between 50 and 200 ppm should be considered as suitable working dilutions; concentrations in excess of 250 ppm should be avoided as precipitation may occur. The dilution should be made on a daily basis immediately prior to provision, preferably in a glass container. The use of a 0.5 ml (100 unit) insulin syringe should be considered for the withdrawal of very small volumes of the product and to facilitate dilution prior to administration. Medicated fluids should be made up immediately prior to provision on a daily basis.

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

In very rare cases, in exotic animals where the recommended dose has been exceeded, neurological signs (ataxia, excitation) can also occur.
Do not exceed the recommended dose. In accidental overdose 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

Official and local antimicrobial policies should be taken into account when the product is used.

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 the instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.

3.12 Withdrawal periods

Calves: Meat and offal: 8 days
Not for use in poultry (chickens and turkeys). Not for use in exotic animals or birds intended for human consumption.

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 stranded 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 are such that both oral and parenteral administration leads to similar serum levels. Enrofloxacin possesses a high distribution volume. Tissue levels 2-3 times higher than 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: 3 years.
Shelf life after first opening the immediate packaging: 28 days.
Shelf life after dilution according to direction: 24 hours.

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

White high density polyethylene bottles closed with polypropylene screw cap.
Container Volumes: 100 ml, 500ml, 1 litre

Not all pack sizes may be marketed.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

7. MARKETING AUTHORISATION NUMBERS

Vm 52127/5160
Vm 52127/3085

8. DATE OF FIRST AUTHORISATION

11 November 1993

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

November 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 17 November 2025