SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril 2.5% Oral Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 Active Constituents	mg per ml
Enrofloxacin	25.0

2.2 Relevant Constituents of the Excipients

Benzyl Alcohol	14.0

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral solution.

4. CLINICAL PARTICULARS

4.1 Target species

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

4.2 Indications for use, specifying the 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-bacillosis 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.

4.3 Contraindications

The product should not be used for prophylaxis.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

i) Special precautions for use in animals

See 4.4.

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.

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

Wear impervious gloves 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.

iii) Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

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

In very rare cases, in exotic animals where the recommended dose has been exceeded, neurological signs (ataxia, excitation) can also occur.

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

4.7 Use during pregnancy, lactation or lay

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.

4.8 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.

Amount(s) to be administered and administration route

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 10 mg enrofloxacin per kg bodyweight (0.4 ml per kg *(excluding chickens* bodyweight) orally diluted in water, twice daily 7 days. *and turkeys)*

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.

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

Do not exceed the recommended dose. In accidental overdose there is no antidote and treatment should be symptomatic.

4.10 Withdrawal period(s)

Calves: Meat: 8 days

Not for use in poultry (chickens and turkeys). Not for use in exotic animals or birds intended for human consumption.

5. PHARMACOLOGICAL PROPERTIES

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

ATC Vet 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 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.

5.2 Pharmacokinetic properties

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium hydroxide
Benzyl alcohol
Hypromellose
Water purified

6.2 Incompatibilities

None known.

6.3 Shelf-life

Unopened Container: 3 years.

Broached Container: Following withdrawal of the first dose, use the product within 28 days. Discard unused material.
Diluted Product: Any medicated liquid remaining 24 hours after preparation must be discarded.

6.4 Special precautions for storage

Do not store above 25^{o}C. Store in a dry place.

6.5 Nature and composition of immediate packaging

Container Material: Container Closure:

High density polyethylene bottles Polypropylene

screw cap

Container Colour: White

Container Volumes:

UK: 100 ml, 500ml (1 litre not currently marketed) Ireland: 100 ml

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

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA

United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 00879/4117

9. DATE OF FIRST AUTHORISATION

11 November 1993

10. DATE OF REVISION OF THE TEXT

September 2023

Approved 15 September 2023