Bayer plc
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Baytril 2.5% Oral Solution

Species:	Ornamental birds, Rabbits, Reptiles, Small mammals, Cattle
Therapeutic indication:	**Pharmaceuticals: Antimicrobials: Oral preparations:** Others
Active ingredient:	Enrofloxacin
Product:	Baytril® 2.5% Oral Solution
Product index:	Baytril 2.5% Oral Solution
Cattle - meat:	8 days
Withdrawal notes:	Not for use in exotic animals or birds for human consumption. Not for use in poultry

Presentation

An oral solution containing 25 mg/ml enrofloxacin as active ingredient and 14 mg/ml benzyl alcohol as excipient.

Uses

Baytril 2.5% Oral Solution is for use in calves for 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.

Baytril 2.5% Oral Solution 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.

Dosage and administration

Calves

Administer via the milk, milk replacer, electrolyte solution or water. The dose rate is 2.5 mg per kg body weight (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

See Table 1.

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.

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.

Table 1: Dosage for Baytril 2.5% Oral Solution

Species	Dosage	Route	Dose Frequency	Treatment period
Small mammals	5 mg enrofloxacin per kg bodyweight (0.2 ml/kg bw)	Orally diluted in water	Twice daily	7 days
Reptiles	5 mg enrofloxacin per kg bodyweight (0.2 ml/kg bw)	Orally diluted in water	24-48 hour intervals	6 days
Birds (excluding chickens and turkeys)	10 mg enrofloxacin per kg bodyweight (0.4 ml/kg bw)	Orally diluted in water	Twice daily	7 days

Baytril 2.5% Oral Solution Table

Use during 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.

Contra-indications, warnings, etc

The product should not be used for prophylaxis.

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

Official and local antimicrobal 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.

Wherever 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.

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

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

Not for use in poultry (chickens and turkeys).

User safety

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.

Withdrawal period(s)

Calves: Meat: 8 days

Not for use in exotic animals or birds intended for human consumption.

Environmental Safety

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

Pharmaceutical precautions

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

Shelf-life of the unopened container: 3 years.

Shelf-life of the broached container: Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

Shelf-life of the diluted product: Any medicated liquid remaining 24 hours after preparation must be discarded.

Further information

Enrofloxacin is a synthetic, broad spectrum antimicrobial substance, belonging to the fluoroquinolone group of antibiotics. ATC Vet Code: QJ01MA90

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.

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.

Legal category

Legal category: POM-V

Packaging quantities

White high density polyethylene bottles with a polypropylene screw cap containing 100 ml.

Marketing Authorisation Number

Vm 00010/4078

Significant changes

GTIN

GTIN description: Baytril 2.5% Oral Solution (100ml)

GTIN: 04007221019251