

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril Piglet Doser 0.5% Oral Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Constituents	mg per ml
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Enrofloxacin	5.0
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Relevant Constituents of the Excipients

Benzyl Alcohol	14.0
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For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral solution.
Clear aqueous solution

4. CLINICAL PARTICULARS

4.1 Target species

Piglets

4.2 Indications for use, specifying the target species

The product is for use in the treatment of diseases of the respiratory and alimentary tracts of bacterial or mycoplasmal origin (e.g. pasteurellosis, mycoplasmosis, coli-bacillosis, coli-septicaemia and salmonellosis), and multifactorial diseases such as atrophic rhinitis and enzootic pneumonia, where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

4.3 Contraindications

Should not be used for prophylaxis.

4.4 Special warnings for each target species

None known

4.5 Special precautions for use

i) Special precautions for use in animals

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

Enrofloxacin may cause hypersensitivity (allergic reactions). People with known hypersensitivity to fluoroquinolones (e.g., enrofloxacin or ciprofloxacin) should avoid any contact with the product.

The product may be irritating to skin and eyes.

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 while using the product.

iii) Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

Slight and transient digestive tract disorders may occur in very rare cases.

4.7 Use during pregnancy, lactation or lay

Not applicable – this product is only indicated for piglets

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, chloramphenicol). The simultaneous application of substances containing Aluminium or Magnesium can impair the absorption of Enrofloxacin.

4.9 Amount(s) to be administered and administration route

Dose rate is 1.5 – 5 mg enrofloxacin/kg bodyweight daily.

The contents of Baytril Piglet Doser are administered orally using the dosing pump. 1 pump stroke delivers 1 ml.

For piglets up to 3 kg bodyweight – 1 ml once daily for 3 to 5 days

For piglets 3 kg up to 10 kg bodyweight – 3 ml once daily for 3 to 5 days

4.10 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.

4.11 Withdrawal period(s)

Piglets: Meat: 10 days

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

It 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 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, 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 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 30 months

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

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Container Material:	High density polyethylene bottles.
Container Closure:	Polypropylene screw cap.
Container Colour:	White.
Container Volumes:	100 ml.
Dosing Device:	Polypropylene/polyethylene/stainless steel pump dispensing 1ml
Secondary pack	Carton

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 00879/4124

9. DATE OF FIRST AUTHORISATION

11 November 1993

10. DATE OF REVISION OF THE TEXT

September 2023

Approved 15 September 2023

