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
Enrofloxacin	5.0

Relevant Constituents of the Excipients

Benzyl Alcohol	14.0

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 casual 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

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, fluoroquinoones 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 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 while using the product.

4.6 Adverse reactions (frequency and seriousness)

Slight and transient digestive tract disorders (such as nausea, vomiting and diarrhoea) 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 interactions

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 Amounts to be administered and administration route

Dose rate is 1.5 – 5.0 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 or IMMUNOLOGICAL PROPERTIES

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

ATC Vet code: QJ01MA90

5.1 Pharmacodynamic properties

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 Pharmacokinetic particulars

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 1 ml
Secondary pack: carton

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

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

7 MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann-Strasse 4
27472 Cuxhaven
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA22020/064/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1988
Date of last renewal: 30 September 2008

10 DATE OF REVISION OF THE TEXT

July 2023