

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Baytril Piglet Doser 0.5% Oral Solution

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

<b>Active Constituents</b>	<b>mg per ml</b>
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Enrofloxacin	5.0
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<b>Relevant Constituents of the Excipients</b>	
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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**

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)**

None known

#### **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**

None known.

#### **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**

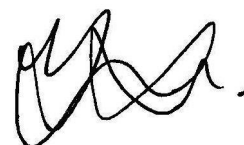
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**9. DATE OF FIRST AUTHORISATION**

11 November 1993

**10. DATE OF REVISION OF THE TEXT**

October 2020



Approved: 08 October 2020