SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril 100 mg/ml solution for use in drinking water for chickens, turkeys and rabbits

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Enrofloxacin 100 mg;

Excipients

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol (E1519)	14 mg
Potassium hydroxide	
Purified water	

Clear yellowish solution.

3. CLINICAL INFORMATION

3.1 Target species

Chickens, turkeys and rabbits.

3.2 Indications for use for each target species

For the treatment of the respiratory tract and of the digestive tract infections caused by the following bacteria:

Chickens:

Avibacterium paragallinarum, Pasteurella multocida, Mycoplasma gallisepticum, Mycoplasma synoviae.,

Turkeys:
Pasteurella multocida, Mycoplasma gallisepticum, Mycoplasma synoviae.

Rabbits:
Pasteurella multocida and bacterial enteritis due to infection with *E.coli*.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, to other fluoroquinolones or to any of the excipients.

3.4 Special warnings

Treatment of *Mycoplasma spp* infections may not eradicate the organism.
Resistance has been reported in *Mycoplasma synoviae* in the EU.
Cross-resistance has been shown between enrofloxacin and other fluoroquinolones in target pathogens, e.g. *Escherichia coli.*
Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to fluoroquinolones because its effectiveness may be reduced.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Not for use for prophylaxis.

Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

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

People with known hypersensitivity to fluoroquinolones should avoid contact with the veterinary medicinal product.
Avoid contact with skin and eyes.
In case of accidental spillage onto skin or eyes, rinse immediately with water, seek medical advice immediately and show the package leaflet to the physician. Wash hands and exposed skin after use.

Do not eat, drink or smoke whilst using the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds:
Do not use in laying hens producing eggs for human consumption.
Do not administer to layer replacement birds within 14 days before the start of the laying period.

3.8 Interaction with other medicinal products and other forms of interaction

In vitro, an antagonism was shown, when combining fluoroquinolones with bacteriostatic antimicrobial agents such as macrolides or tetracyclines and phenicols. The simultaneous application of substances containing aluminium or magnesium can impair the absorption of enrofloxacin.

3.9 Administration routes and dosage

In drinking water use.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Always make sure that the entire dose offered has been consumed. The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of enrofloxacin may need to be adjusted accordingly. The medicated water should be made up fresh each day just before it is offered to the animals. The drinking water must be medicated throughout the treatment period, and no other water source should be available.
Use only fresh pre-solutions, prepared every day before start of treatment. Pumping systems should be checked constantly to assure proper medication. Empty the water system and fill it with medicated water before starting the treatment.

The veterinary medicinal product may be put directly into the header tank or introduced via a water proportioner pump.

Chickens and turkeys:

10 mg enrofloxacin/kg bodyweight per day for 3-5 consecutive days.
Treatment for 3-5 consecutive days; for 5 consecutive days in mixed infections and chronic progressive forms

Based on the recommended dose and the number and weight of animals to be treated, the exact daily quantity of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{0.1\ ml\ of\ veterinary\ medicinal\ product \times average\ body\ weight\ (kg)\ of\ animals\ to\ be\ treated}{average\ daily\ water\ intake\ (l/animal)}$$

$$= ml\ veterinary\ medicinal\ product\ per\ litre\ of\ drinking\ water$$

Rabbits:
10 mg/kg bodyweight per day for 5 consecutive days.
Based on the recommended dose and the number and weight of animals to be treated, the exact daily quantity of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{0.1\ ml\ of\ veterinary\ medicinal\ product \times average\ body\ weight\ (kg)\ of\ animals\ to\ be\ treated}{average\ daily\ water\ intake\ (l/animal)}$$

$$= ml\ veterinary\ medicinal\ product\ per\ litre\ of\ drinking\ water$$

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse clinical symptoms were observed in chickens and turkeys treated respectively with doses up to 10 and 6 times higher than the therapy dose.
The use of fluoroquinolones during the growth phase combined with a marked and prolonged increase in the intake of drinking water, and hence active ingredient, possibly due to high temperatures, may potentially be associated with damage of the articular cartilage.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Chickens: Meat and offal: 7 days.
Turkeys: Meat and offal: 13 days.
Rabbits: Meat and offal: 3 days.
Not for use in birds producing eggs for human consumption'
Do not administer to layer replacement birds within 14 days before the start of the laying period.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01MA90

4.2 Pharmacodynamics

Mode of action:

Two enzymes essential in DNA replication and transcription, DNA gyrase and topoisomerase IV, have been identified as the molecular targets of fluoroquinolones. They modulate the topological state of DNA through cleaving and resealing reactions. Initially, both strands of the DNA double helix are cleaved. Then, a distant segment of DNA is passed through this break before the strands are resealed. Target inhibition is caused by noncovalent binding of fluroquinolone molecules to an intermediate state in this sequence of reactions, in which DNA is cleaved, but both strands are retained covalently attached to the enzymes. Replication forks and translational complexes cannot proceed beyond such enzyme-DNA-fluroquinolone complexes, and inhibition of DNA and mRNA synthesis triggers events resulting in a rapid, drug concentration-dependant killing of pathogenic bacteria.

Antibacterial spectrum:

Enrofloxacin is active against many Gram-negative bacteria, against Gram-positive bacteria and *Mycoplasma* spp.
In vitro susceptibility has been shown in strains of (i) Gram-negative species such as *Avibacterium* (*Haemophilus*) *paragallinarum and Pasteurella multocida* and (ii) *Mycoplasma gallisepticum* and *Mycoplasma synoviae*.(See section 3.5).

Types and mechanisms of resistance:

Resistance to fluoroquinolones has been reported to arise from five sources, (i) point mutations in the genes encoding for DNA gyrase and/or topoisomerase IV leading to alterations of the respective enzyme, (ii) alterations of drug permeability in Gram-negative bacteria, (iii) efflux mechanisms, (iv) plasmid mediated resistance and (v) gyrase protecting proteins. All mechanisms lead to a reduced susceptibility of the bacteria to fluoroquinolones. Cross-resistance within the fluoroquinolone class of antimicrobials is common.

Resistance of Mycoplasma gallisepticum and Mycoplasma synoviae to enrofloxacin has been reported in chickens and turkeys

4.3 Pharmacokinetics

Enrofloxacin administered via drinking water to poultry is rapidly and very well absorbed with a bioavailability of approx. 90 %. Maximum plasma concentrations of 2 mg/l are reached within 1.5 hours after a single bolus dose rate of 10 mg/kg body weight with a total systemic availability of 14.4 mg.hr/l . Enrofloxacin is eliminated from the body with a total body clearance of 10.3 ml/min.kg. If dosed as continuous drinking water medication (multiple dosing) steady-state concentrations of 0.5 mg (turkeys) to 0.8 mg (chicken) enrofloxacin per litre are achieved. A high mean volume of distribution (5 l/kg) indicated good tissue penetration of enrofloxacin. Concentrations in target tissues like lungs, liver, kidney, intestine and muscle tissue, exceed plasma concentrations by far. In poultry enrofloxacin is poorly metabolised to its active metabolite ciprofloxacin (approximately 5%).
Enrofloxacin is eliminated from the body at a half-life of 6 hours. Protein binding in poultry is approximately 25%.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing biocidal products, feed additives or other substances used in drinking water.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.
Shelf life after first opening the immediate packaging: 12 weeks.
Shelf life after dilution according to directions: 24 hours.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

100 ml, 500 ml and 1,000 ml high density polyethylene (HDPE) bottles with an HDPE insert and a polypropylene screw closure.
5,000 ml HDPE canister with an aluminium/HDPE seal and an HDPE screw closure.
The containers are provided with a graduated polypropylene measuring cup.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

7. MARKETING AUTHORISATION NUMBER

Vm 52127/5104

8. DATE OF FIRST AUTHORISATION

11 November 1993

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

December 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.
Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 08 May 2026