# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril 50 mg/ml solution for injection

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

**Active substance:** Enrofloxacin 50 mg

| **Qualitative composition of excipients and other constituents** | **Quantitative composition if that information is essential for proper administration of the veterinary medicinal product** |
|---|---|
| n-Butyl alcohol | 30 mg |
| Potassium hydroxide | |
| Water for injections | |

Clear light-yellow solution

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cattle (calves), sheep, goats, pigs, dogs and cats.

### 3.2 Indications for use for each target species

**Calves**
Treatment of infections of the respiratory tract caused by strains of *Mannheimia haemolytica Pasteurella multocida,* and *Mycoplasma* spp.
Treatment of infections of the alimentary tract caused by strains of *Escherichia coli*.
Treatment of septicaemia caused by strains of *Escherichia coli*.
Treatment of acute mycoplasma-associated arthritis due to strains of *Mycoplasma bovis*

**Sheep**
Treatment of infections of the alimentary tract caused by strains of *Escherichia coli*.
Treatment of septicaemia caused by strains of *Escherichia coli*.
Treatment of mastitis caused by strains of *Staphylococcus aureus* and *Escherichia coli*.

**Goats**
Treatment of infections of the respiratory tract caused by strains of *Mannheimia haemolytica* and *Pasteurella multocida.*
Treatment of infections of the alimentary tract caused by strains of *Escherichia coli*.
Treatment of septicaemia caused by strains of *Escherichia coli*.
Treatment of mastitis caused by strains of *Staphylococcus aureus* and *Escherichia coli*.

**Pigs**
Treatment of infections of the respiratory tract caused by strains of *Actinobacillus pleuropneumoniae, Pasteurella multocida andMycoplasma* spp.
Treatment of infections of the alimentary tract caused by strains of *Escherichia coli*.
Treatment of septicaemia caused by strains of *Escherichia coli.*

**Dogs**
Treatment of infections of the alimentary, respiratory and urogenital tracts (including prostatitis, adjunctive antibiotic therapy for pyometra), skin and wound infections, otitis (externa/media) caused by strains of *Staphylococcus* spp*., Escherichia coli, Bordetella* spp*, Klebsiella* spp*., Pasteurella* spp*., Proteus* spp*. and Pseudomonas* spp*.*

**Cats**
Treatment of infections of the alimentary, respiratory and urogenital tracts (as adjunctive antibiotic therapy for pyometra), skin and wound infections, caused by strains of *Staphylococcus* spp*., Escherichia coli, Bordetella* spp*., Proteus* spp. and *Pseudomonas* spp*.*

## 3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, to other fluoroquinolones or to any of the excipients
Do not use in animals with central nervous system-associated seizure disorders.

Do not use in the presence of existing disorders of cartilage development or musculoskeletal damage around functionally significant or weight-bearing joints
Do not use in young dogs during their growth, i.e. in small breeds of dogs less than 8 months of age, in big breeds of dogs less than 12 months of age, in giant breeds of dogs less than 18 months of age.
Do not use in cats less than 8 weeks of age.

Do not use in growing horses because of possible deleterious damage on articular cartilage.

## 3.4 Special warnings

Cross-resistance has been shown between enrofloxacin and other (fluoro)quinolones 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.

A high resistance rate of *Pseudomonas* spp. to enrofloxacin (up to 99%) has been reported in dogs in Europe. Enrofloxacin should only be used for treatment of infections caused by this pathogen following susceptibility testing.

## 3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

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.

The veterinary medicinal product should only be used in individual animals

Special caution should be taken when using enrofloxacin in animals with impaired renal function.

Special caution should be taken when using enrofloxacin in cats because higher doses than recommended can cause retinal damage and blindness. For cats weighing less than 5 kg, the dosage of 25 mg/ml is more appropriate to avoid risk of overdosage (see section 3.10).

Degenerative changes of articular cartilage were observed in calves treated orally with 30 mg enrofloxacin/kg body weight during 14 days.

The use of enrofloxacin in growing lambs at the recommended dose for 15 days caused histological changes in the articular cartilage, not associated to clinical signs.

Not for use for prophylaxis.

Special precautions to be taken by the person administering the veterinary 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 veterinary medicinal product.
The product may be irritating to skin and eyes. In case of contact with skin or eyes, wash the affected area with clear running water.
Wash hands after use. Do not eat, drink or smoke whilst handling the product.
Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

In countries where feeding of fallen stock to scavenger bird populations is permitted as a conservation measure (see Commission Decision 2003/322/EC), the possible risk to hatching success should be considered before feeding carcasses of livestock recently treated with this product.

## 3.6 Adverse events

Calves.

| | |
|---|---|
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Injection site reaction[1,2]<br>Digestive tract disorders (e.g. Diarrhoea)[2,3] |

[1] Local tissue reactions observed up to 14 days.
[2] Transient
[3] Mild

Sheep and goats.

| | |
|---|---|
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Digestive tract disorders (e.g. Diarrhoea)[1] |

[1] Mild and transient

Pigs.

| | |
|---|---|
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Injection site inflammation[1]<br>Digestive tract disorders (e.g. Diarrhoea)[2] |

[1] May occur after intramuscular administration and persist for up to 28 days after the injection.
[2] Mild and transient

Dogs.

| | |
|---|---|
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Injection site oedema[1,2]<br>Digestive tract disorders (e.g. Diarrhoea)[2,3] |

[1] Moderate
[2] Transient
[3] Mild

Cats.

| | |
|---|---|
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Digestive tract disorders (e.g. Diarrhoea)[1] |

[1] Mild and transient

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

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effects but have shown evidence of foetotoxic effects at maternotoxic doses.

Pregnancy and lactation:
Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

### 3.8 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 or phenicols).

Do not use concurrently with theophylline as the elimination of theophylline may be delayed.
Care should be taken during the concomitant use of flunixin and enrofloxacin in dogs to avoid adverse drug reactions. The decrease in drug clearances as a result of co-administration of flunixin and enrofloxacin indicates that these substances interact during the elimination phase. Thus, in dogs, the co-administration of enrofloxacin and flunixin increased the AUC and the elimination half-life of flunixin and increased the elimination half-life and reduced the $C_{max}$ of enrofloxacin.

## 3.9 Administration routes and dosage

Intravenous (i.v.), subcutaneous (s.c.) or intramuscular (i.m.) use.
Repeated injections should be made at different injection sites.
To ensure a correct dosage, body weight (bw) should be determined as accurately as possible.

Calves
5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily for 3-5 days.
Acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis*: 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily for 5 days.
The veterinary medicinal product can be administered by slow intravenous or subcutaneous administration.
Not more than 10 ml should be administered at one subcutaneous injection site.

Sheep and goats
5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily by subcutaneous injection for 3 days.
Not more than 6 ml should be administered at one subcutaneous injection site.

Pigs
2.5 mg of enrofloxacin/kg bw, corresponding to 0.5 ml/10 kg bw, once daily by intramuscular injection for 3 days.
Alimentary tract infection or septicaemia caused by *Escherichia coli*: 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily by intramuscular injection for 3 days.
In pigs, the injection should be made in the neck at the ear base.
Not more than 3 ml should be administered at one intramuscular injection site.

Dogs and cats
5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily by subcutaneous injection for up to 5 days.
Treatment may be initiated with injectable product and maintained with enrofloxacin tablets. Duration of treatment should be based on the duration of treatment approved for the appropriate indication in the product information of the tablet product.

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

In cases of accidental overdoses digestive tract disorders (e.g. vomiting, diarrhoea) and neurological disorders may occur.

In pigs, no adverse effects were reported after the administration of 5 times the recommended dose.

Cats have been shown to suffer ocular damage after receiving doses of more than 15 mg/kg once daily for 21 consecutive days. Doses of 30 mg/kg given once daily for 21 consecutive days have been shown to cause irreversible ocular damage. At 50 mg/kg given once daily for 21 consecutive days, blindness can occur.

In dogs, cattle, sheep and goats, overdose has not been documented.

In accidental overdose there is no antidote and treatment should be symptomatic.

### 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

Cattle:
Meat and offal:
**s.c.**: 12 days
**i.v.**: 5 days
Milk: Not authorised for use in animals producing milk for human consumption.

Sheep:
Meat and offal: 4 days.
Milk: 3 days.

Goats:
Meat and offal: 6 days.
Milk: 4 days.

Pigs:
Meat and offal: 13 days.

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code: QJ01MA90

### 4.2 Pharmacodynamics

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

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. Target inhibition is caused by non-covalent binding of fluoroquinolone molecules to these enzymes. Replication forks and translational complexes cannot proceed beyond such enzyme-DNA-fluoroquinolone complexes, and inhibition of DNA and mRNA synthesis triggers events resulting in a rapid, drug concentration-dependent killing of pathogenic bacteria. The mode of action of enrofloxacin is bactericidal and bactericidal activity is concentration dependent.

Antibacterial spectrum

Enrofloxacin is active against many Gram-negative bacteria such as *Escherichia coli*, *Klebsiella* spp., *Actinobacillus pleuropneumoniae*, *Mannheimia haemolytica*, *Pasteurella* spp. (e.g. *Pasteurella multocida*), *Bordetella* spp., *Proteus* spp., *Pseudomonas* spp., against Gram-positive bacteria such as *Staphylococcus* spp. (e.g. *Staphylococcus aureus*) and against *Mycoplasma* spp. at the recommended therapeutic doses.

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.

**MIC clinical breakpoints**

Cattle:

Clinical breakpoints established by CLSI[1] in 2024 for enrofloxacin in cattle for bovine respiratory disease are as follows:

| Organism | Minimum inhibitory concentration breakpoints of enrofloxacin (µg/ml) | | |
|---|---|---|---|
| | susceptible | intermediate | resistant |
| *Mannheimia haemolytica* | ≤0.25 | 0.5-1 | ≥2 |
| *Pasteurella multocida* | ≤0.25 | 0.5-1 | ≥2 |

[1] CLSI. Performance standards for antimicrobial disk and dilution susceptibility tests for bacteria isolated from animals: 7th ed. CLSI supplement Vet01S Clinical and Laboratory Standards Institute

Pig:

Clinical breakpoints established by CLSI[1] in 2024 for enrofloxacin in pigs for porcine respiratory disease are as follows:

| Organism | Minimum inhibitory concentration breakpoints of enrofloxacin (µg/ml) | | |
|---|---|---|---|
| | susceptible | intermediate | resistant |
| *Actinobacillus pleuropneumoniae* | ≤0.25 | 0.5 | ≥1 |
| *Pasteurella multocida* | ≤0.25 | 0.5 | ≥1 |

[1] CLSI. Performance standards for antimicrobial disk and dilution susceptibility tests for bacteria isolated from animals: 7th ed. CLSI supplement Vet01S Clinical and Laboratory Standards Institute

Dog:
Clinical breakpoints established by CLSI[1] in 2024 for enrofloxacin in dogs for canine respiratory disease, urinary tract, skin and soft tissue infection are as follows:

| Organism | Minimum inhibitory concentration breakpoints of enrofloxacin (µg/ml) | | |
|---|---|---|---|
| | susceptible | intermediate | resistant |
| *Staphylococcus* spp. | ≤0.06 | - | ≥0.5 |
| *Pseudomonas aeruginosa* | ≤0.06 | - | ≥0.5 |
| *Escherichia coli* | ≤0.06 | - | ≥0.5 |
| *Proteus mirabilis* (urinary tract, skin and soft tissue infection) | ≤0.06 | - | ≥0.5 |
| *Klebsiella pneumoniae* (urinary tract infection) | ≤0.06 | - | ≥0.5 |

[1] CLSI. Performance standards for antimicrobial disk and dilution susceptibility tests for bacteria isolated from animals: 7th ed. CLSI supplement Vet01S Clinical and Laboratory Standards Institute.

Cat:
Clinical breakpoints established by CLSI[1] in 2024 for enrofloxacin in cats for feline skin and soft tissue infection are as follows:

| Organism | Minimum inhibitory concentration breakpoints of enrofloxacin (µg/ml) | | |
|---|---|---|---|
| | susceptible | intermediate | resistant |
| *Staphylococcus* spp. | ≤0.5 | 1-2 | ≥4 |
| *Escherichia coli* | ≤0.5 | 1-2 | ≥4 |

[1] CLSI. Performance standards for antimicrobial disk and dilution susceptibility tests for bacteria isolated from animals: 7th ed. CLSI supplement Vet01S Clinical and Laboratory Standards Institute.

**4.3 Pharmacokinetics**
Enrofloxacin is rapidly absorbed after parenteral injection. Bioavailability is high (approximately 100% in pig and cattle) with a low to moderate plasma protein binding (approximately 20 to 50%). Enrofloxacin is metabolized to the active substance ciprofloxacin at approximately 40 % in dogs and ruminants, less than 10 % in pigs and cats.

Enrofloxacin and ciprofloxacin distribute well into all target tissues, e.g. lung, kidney, skin, and liver, reaching 2- to 3-fold higher concentrations than in plasma. Parent substance and active metabolite are cleared from the body via urine and faeces.
Accumulation in plasma does not occur following a treatment interval of 24 h.
In milk, most of drug activity consists on ciprofloxacin. Overall drug concentrations peak at 2 hours after treatment showing an approximately 3-fold higher total exposure over the 24 hours dosing interval compared to plasma.

| | Dogs | Cats | Pigs | Pigs | Cattle | Calves |
|---|---|---|---|---|---|---|
| Dose rate (mg/kg bw) | 5 | 5 | 2.5 | 5 | 5 | 5 |
| Route of administration | sc | sc | im | im | iv | sc |
| $T_{max}$ (h) | 0.5 | 2 | 2 | 2 | / | 1.2 |
| $C_{max}$ (mcg/ml) | 1.8 | 1.3 | 0.7 | 1.6 | / | 0.73 |
| AUC (mcg·h/ml) | / | / | 6.6 | 15.9 | 7.11 | 3.09 |
| Terminal half-life (h) | / | / | 13.12 | 8.10 | / | 2.34 |
| Elimination half-life (h) | 4.4 | 6.7 | 7.73 | 7.73 | 2.2 | / |
| F (%) | / | / | 95.6 | / | / | / |

## 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.

### 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: 28 days.

### 5.3 Special precautions for storage

Do not refrigerate or freeze.

### 5.4 Nature and composition of immediate packaging

Brown glass (type I) vials with a chlorobutyl polytetrafluoroethylene (PTFE) stopper and with a flip- off cap with aluminium case and plastic flip-off button.

Pack-sizes:
50 ml and 100 ml in a cardboard box.

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 52127/5120

## 8. DATE OF FIRST AUTHORISATION

22 April 1992

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

January 2026

## 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: 13 April 2026