SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril 100 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substance: Enrofloxacin 100 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, sheep, goats and pigs.

3.2 Indications for use for each target species

Cattle
Treatment of infections of the respiratory tract caused by strains of *Mannheimia haemolytica* Pasteurella multocida and *Mycoplasma* spp.
Treatment of acute severe mastitis caused by strains of *Escherichia coli*.
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* in cattle less than 2 years old.

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* and *Mycoplasma* spp.
Treatment of infections of the urinary tract caused by strains of *Escherichia coli.*
Treatment of post-partum dysgalactiae syndrome, PDS (MMA syndrome) caused by strains of *Escherichia coli* and *Klebsiella* spp.
Treatment of infections of the alimentary tract caused by strains of *Escherichia coli.*
Treatment of septicaemia caused by strains of *Escherichia coli*.

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 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.

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

The feeding of waste milk containing residues of enrofloxacin to calves should be avoided up to the end of the milk withdrawal period (except during the colostral phase), because it could select antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria.

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 product including use deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to enrofloxacin and may decrease the effectiveness of treatment with all fluoroquinolones due to the potential for cross-resistance.

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 with 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 veterinary medicinal 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 veterinary medicinal product.

3.6 Adverse events

Cattle, sheep, goats and pigs.

Rare (1 to 10 animals / 10,000 animals treated):	Injection site inflammation[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Excitation Circulatory shock[2] Digestive tract disorder (e.g. diarrhoea)[3] Anaphylaxis Ataxia, Seizure, Tremor

[1] In pigs, after intramuscular administration. May persist up to 28 days after injection.
[2] In cattle, after intravenous administration.
[3] 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

Pregnancy and Lactation**:**

Cattle:

The safety of the veterinary medicinal product has been established in pregnant cows during the 1st quarter of pregnancy. The veterinary medicinal product can be used in pregnant cows during the 1st quarter of pregnancy.
The use of the veterinary medicinal product in cows during the 3 last quarters of pregnancy should be based on a benefit-risk assessment by the responsible veterinarian.
Can be used during lactation.

Sheep and goats:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit-risk assessment by the responsible veterinarian.

Pigs:

The safety of the veterinary medicinal product has not been established during pregnancy. Use only according to the benefit-risk assessment by the

responsible veterinarian.
Can be used during lactation

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.

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.

Cattle
5 mg of enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, once daily for 3–5 days.

Acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis* in cattle less than 2 years old: 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, once daily for 5 days.

The veterinary medicinal product can be administered by slow intravenous or subcutaneous administration.

Acute mastitis caused by *Escherichia coli*: 5 mg enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, by slow intravenous injection once daily for two consecutive days.
The second dose may be administered by the subcutaneous route. In this case, the withdrawal period following subcutaneous injection applies.

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/20 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/20 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/20 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.

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.

In cattle, sheep and goat, 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:
s.c.: 4 days
i.v.: 3 days

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*), 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

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 ruminants and less than 10% in pigs.
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.

	Pigs	Pigs	Cattle	Cattle
Dose rate (mg/kg bw)	2.5	5	5	5
Route of administration	im	im	iv	sc
T_{max} (h)	2	2	/	3.5
C_{max} (mcg/ml)	0.7	1.6	/	0.733
AUC (mcg·h/ml)	6.6	15.9	9.8	5.9
Terminal half-life (h)	13.12	8.10	/	7.8
Elimination half-life (h)	7.73	7.73	2.3	
F (%)	95.6	/	/	88.2

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 NUMBERS

UK(GB): Vm 52127/5121
UK(NI): Vm 52127/3046

8. DATE OF FIRST AUTHORISATION

11 November 1993

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: 15 June 2026