1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril 25 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Enrofloxacin: 25 mg

Excipients:

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

Dogs, cats, pigs (piglets), rabbits, rodents, reptiles and ornamental birds.

3.2 Indications for use for each target species

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*., Klebsiella* spp*., Pasteurella* spp*., Proteus* spp. and *Pseudomonas* spp.

Pigs (piglets)
Treatment of infections of the respiratory tract caused by strains of: *Actinobacillus pleuropneumoniae*, *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*.

Rabbits
Treatment of infections of the alimentary and respiratory tracts caused by strains of: *Staphylococcus* spp., *Escherichia coli* and *Pasteurella multocida*.
Treatment of skin and wound infections caused by strains of *Staphylococcus aureus.*

Rodents, reptiles and ornamental birds
Treatment of infections of the alimentary and respiratory tracts where clinical experience, if possible, supported by susceptibility testing of the causal organism, indicates enrofloxacin as the substance of choice.

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.

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 (in some cases, higher than 90%) 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 (see section 3.10).

Not for use for prophylaxis.

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 skin and eye contact. Wash any splashes from skin or eyes immediately with 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

Dogs, cats, pigs (piglets), rabbits, rodents, reptiles and ornamental birds.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site inflammation[1], Injection site reaction (e.g. oedema)[2], Injection site reddening[3], Injection site ulcer[3,4] Excitation Digestive tract disorders (e.g. diarrhoea, vomiting)[5] Anaphylaxis Ataxia, Seizure, Tremor Bruising[6] Anorexia[5]

[1] In pigs, after intramuscular administration. May persist up to 28 days after injection.
[2] In dogs. Moderate and transient.
[3] In rabbits. May persist at least up to 17 days after injection.
[4] With deep loss of tissue.
[5] Mild and transient.
[6] In reptiles and ornamental birds. Of muscles.

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. The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

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

Laying birds and reptiles:
The safety of the veterinary medicinal product has not been established during lay. Use only according 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

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.

Dogs and cats:
5 mg of enrofloxacin/kg bw, corresponding to 1 ml/5 kg bw, 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.

Pigs (piglets):
2.5 mg of enrofloxacin/kg bw, corresponding to 1 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 of bw, corresponding to 2 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.

Rabbits:
10 mg of enrofloxacin/kg bw, corresponding to 2 ml/5 kg bw, once daily by subcutaneous injection for 5 to 10 consecutive days.

Rodents:
10 mg of enrofloxacin/kg bw, corresponding to 0.4 ml/kg bw, once daily by subcutaneous injection for 5 to 10 consecutive days. If necessary, depending on the severity of clinical signs, this dosage can be doubled.

Reptiles:
Reptiles are ectothermic, relying on external heat sources to maintain their body temperature at the optimum level for correct function of all body systems. Metabolism of substances and activity of the immune system are, thus, critically dependent on the body temperature. Therefore, the veterinarian must be aware of the correct temperature requirements of the respective reptile species and the hydration status of the individual patient. Furthermore, it has to be considered that large differences exist in the pharmacokinetic behaviour of enrofloxacin among different species, which additionally will influence the decision about the correct dosage of the veterinary medicinal product. Therefore, the recommendations made here can only be used as a starting point for individual dose setting.
5–10 mg of enrofloxacin/kg bw, corresponding to 0.2–0.4 ml/kg bw, once daily by intramuscular injection for 5 consecutive days.
An extension of the treatment interval to 48 hours may be necessary in individual cases. In complicated infections, higher dosages and longer treatment courses may be necessary. The presence of the renal portal system in reptiles means it is prudent to administer substances in the front half of the body wherever possible.

Ornamental birds:
20 mg of enrofloxacin/kg bw, corresponding to 0.8 ml/kg bw**,** once daily by intramuscular injection for 5 to 10 consecutive days. In case of complicated infections higher doses may be necessary.

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

In cases of accidental overdose, 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, rabbits, small rodents, reptiles and birds, 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

Pigs:
Meat and offal: 13 days.

Rabbits:
Meat and offal: 6 days.

Do not use in birds intended for human consumption.

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*, *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

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 pigs) 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 less than 10% in cats and pigs.
African Grey Parrots serum ciprofloxacin concentrations were 3–78% of the enrofloxacin dose, with an increasing ciprofloxacin/enrofloxacin ratio with multiple doses.

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.

	Dogs	Cats	Rabbits	Pigs	Pigs
Dose rate (mg/kg bw)	5	5	10	2.5	5
Route of administration	sc	sc	sc	im	im
T_{max} (h)	0.5	2	/	2	2
C_{max} (mcg/ml)	1.8	1.3	/	0.7	1.6
AUC (mcg·h/ml)	/	/	/	6.6	15.9
Terminal half-life (h)	/	/	/	13.12	8.10
Elimination half-life (h)	4.4	6.7	2.5	7.73	7.73
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:
Pack sizes to be completed nationally.
Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

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(S)

VPA22020/044/001

8. DATE OF FIRST AUTHORISATION

01/10/1988

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

10/02/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).