1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril Max 100 mg/ml Solution for Injection for Cattle and Pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
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**
n-Butanol	30 mg
Benzyl alcohol (E1519)	20 mg
Arginine	
Water for injections	

Clear, yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, Pigs.

3.2 Indications for use for each target species

Cattle:
For the treatment of respiratory tract infections caused by *Histophilus somni, Mannheimia haemolytica, Pasteurella multocida* and *Mycoplasma* spp.
For the treatment of mastitis caused by *E. coli*.

Pigs:
For the treatment of bacterial bronchopneumonia caused by *Actinobacillus pleuropneumoniae*, *Pasteurella multocida* and complicated by *Haemophilus parasuis* as a secondary pathogen in pigs.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, other (fluoro)quinolones 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.

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:
For repeated injection or for injection volumes exceeding 15 ml (cattle) or 7.5 ml (pigs, calves) in divided doses, a new site must be chosen for each injection.
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 veterinary medicinal product deviating from the instructions given in this 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.

Enrofloxacin is eliminated renally. As with all fluoroquinolones, delayed excretion can therefore be expected in the presence of existing renal damage.
Not for use for prophylaxis.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Direct contact with the skin should be avoided due to sensitisation, contact dermatitis and possible hypersensitivity reactions.
People with known hypersensitivity to (fluoro)quinolones should avoid contact with the veterinary medicinal product. Wash hands after use.
In the event of accidental splash into the eye, rinse with large amounts of clean water. If irritation occurs, seek medical advice.
Do not eat, drink or smoke while handling the veterinary medicinal product.
Take care to avoid accidental self-injection.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle and pigs:

Rare (1 to 10 animals / 10 000 animals treated):	Injection site reddening[1], Injection site swelling[1] Circulatory shock[2]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Digestive tract disorders[3]

[1] Transitory, regress within a few days without further therapeutic measures.
[2] With intravenous treatment in cattle.
[3] In calves.

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 its local representative, 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:
Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Antagonist effects due to concurrent administration of macrolides and tetracyclines may occur.
Enrofloxacin may interfere with the metabolism of theophylline, decreasing theophylline clearance resulting in increased plasma levels of theophylline.

3.9 Administration routes and dosage

Cattle:
Subcutaneous use (respiratory disease) or Intravenous use (*E. coli* mastitis).

The dosage for respiratory disease is 7.5 mg enrofloxacin per kg body weight (BW) for a single treatment by subcutaneous administration (**s.c.**).

This is equivalent to:

7.5 ml of the veterinary medicinal product per 100 kg BW and day

Do not administer more than 15 ml (cattle) or 7.5 ml (calf) per injection site (**s.c.**).
In case of serious or chronic respiratory disease a second injection may be required after 48 hours.

The dosage for the treatment of *E. coli* mastitis is 5 mg enrofloxacin per kg body weight (BW) by intravenous administration (**i.v.**).

This is equivalent to:

5 ml of the veterinary medicinal product per 100 kg BW and day

The treatment of *E. coli* mastitis should be exclusively by intravenous application on 2 to 3 consecutive days.

Pigs:
Intramuscular use.

The dosage for respiratory tract infections is 7.5 mg enrofloxacin per kg body weight for a single treatment by intramuscular administration (**i.m.**) into the neck muscles behind the ear.

This is equivalent to:

0.75 ml of the veterinary medicinal product per 10 kg BW and day

Do not administer more than 7.5 ml per injection site (**i.m.**). In cases of serious or chronic respiratory disease a second injection may be required after 48 hours.

Repeated injections should be made at different injection sites.

To ensure a correct dosage, body weight should be determined as accurately as possible.
The stopper may be safely punctured up to 20 times.

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

In cattle a dose of 25 mg/kg bodyweight administered by the subcutaneous route for 15 consecutive days is tolerated without any clinical symptoms. Higher doses in cattle and doses of around 25 mg/kg and above in pigs may cause lethargy, lameness, ataxia, slight salivation and muscle tremors.

Do not exceed the recommended dose. 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.: 14 days
i.v.: 7 days

Milk:
s.c.: 120 hours
i.v.: 72 hours

Pigs:
Meat and offal: **i.m.**: 12 days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01MA90

4.2 Pharmacodynamics

Mode of action

Enrofloxacin belongs to the fluoroquinolone group of antibiotics. 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 Gram-positive and many Gram-negative bacteria such as *Histophilus somni, Mannheimia haemolytica, Pasteurella multocida, Mycoplasma* spp. and *E. coli* in cattle as well as *Actinobacillus pleuropneumoniae*, *Pasteurella multocida* and *Haemophilus parasuis* in pigs 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.

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
Histophilus somni	≤0.25	0.5-1	≥2
Mannheimia haemolytica	≤0.25	0.5-1	≥2
Pasteurella multocida	≤0.25	0.5-1	≥2

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

Following subcutaneous administration of the veterinary medicinal product in cattle or intramuscular administration in pigs, the active substance, enrofloxacin, is absorbed very rapidly and almost completely (high bioavailability).

Cattle:

After subcutaneous administration at a dose rate of 7.5 mg enrofloxacin per kg body weight to non- lactating cattle peak plasma concentrations of 0.82 mg/L are reached within 5 hours. The overall drug exposure in plasma is 9.1 mg*hr/L. Enrofloxacin is eliminated from the body at a half-life of 6.4 hr. Approximately 50% of enrofloxacin is metabolised to the active substance ciprofloxacin. Ciprofloxacin is eliminated from the body at a half-life of 6.8 hr.

After intravenous injection at a dose rate of 5.0 mg enrofloxacin per kg body weight to lactating cows, peak plasma concentrations of approx. 23 mg/L are reached immediately. The overall drug exposure in plasma is 4.4 mg*hr/L. Enrofloxacin is eliminated from the body at a half-life of 0.9 hr. Approximately 50% of parent compound is metabolised to ciprofloxacin with peak plasma concentrations of 1.2 mg/L reached at 0.2 hr. Mean elimination half-life of ciprofloxacin is 2.1 hr.

In milk the metabolite ciprofloxacin mainly accounts for antibacterial activity (approx. 90%). Ciprofloxacin reaches peak milk concentrations of 4 mg/L within 2 hr after intravenous dosing. Total exposure in milk over 24 hours is approx. 21 mg*hr/L. Ciprofloxacin is eliminated from milk at a half- life of 2.4 hr. Peak concentrations of 1.2 mg enrofloxacin per litre are reached in milk within 0.5 hours with a total enrofloxacin exposure in milk of approx. 2.2 mg*hr/L. Enrofloxacin is eliminated from milk at 0.9 hr.

Pigs:
After intramuscular administration of 7.5 mg/kg body weight to pigs a mean peak serum concentration of 1.46 mg/L was achieved within 4 hours. The overall drug exposure over 24 hours was 20.9 mg*hr/L. The drug was eliminated from the central compartment at a terminal half-life of 13.1 hr. With peak concentrations less than 0.06 mg/L mean serum concentrations of ciprofloxacin were very low.
Enrofloxacin has a high volume of distribution. The concentrations in the tissues and organs mostly significantly exceed serum levels. Organs in which high concentrations can be expected include the lungs, liver, kidneys, gut and muscle tissue.
Enrofloxacin is eliminated renally.

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: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Protect from frost.

5.4 Nature and composition of immediate packaging

Cardboard box with 1 brown glass bottle (glass type I, Ph. Eur.) of 100 ml with a chlorobutyl stopper secured by an aluminium crimp cap.

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)

VPA22020/053/001

8. DATE OF FIRST AUTHORISATION

23/11/2012

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

08/08/2025

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*).