1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ROXACIN 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**
Benzyl alcohol (E1519)	7.8 mg
Disodium edetate	10.0 mg
Potassium hydroxide (for pH-adjustment)	
Glacial acetic acid	
Water for injections	

Clear slightly yellowish solution

3. CLINICAL INFORMATION

3.1. Target species

Cattle and pigs.

3.2. Indications for use for each target species

Treatment of bacterial infections caused by strains susceptible to enrofloxacin.

Cattle:

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mannheimia haemolytica* and *Mycoplasma* spp.

Treatment of acute severe mastitis caused by enrofloxacin susceptible strains of *Escherichia coli.*

Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.

Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.

Treatment of acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis* in cattle less than 2 years old.

Pigs:

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mycoplasma* spp. and *Actinobacillus pleuropneumoniae.*

Treatment of infections of the urinary tract caused by enrofloxacin susceptible strains of *Escherichia coli.*

Treatment of post-partum dysgalactiae syndrome, PDS (MMA syndrome) caused by enrofloxacin susceptible strains of *Escherichia coli* and *Klebsiella* spp.

Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.

Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.

3.3. Contraindications

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 for prophylaxis.

Do not use in known cases of resistance against other fluoroquinolone due to the potential for cross-resistance.

3.4. Special warnings

None.

3.5. Special precautions for use

Special precautions for safe use in the target species:

The safety of the veterinary medicinal product has not been established in pigs or calves when administered by the intravenous route and use of this route of administration is not recommended in these animal groups

Do not exceed the recommended dose.

Repeat injections should be administered at different sites.

Enrofloxacin should be used with caution in epileptic animals or animals affected by renal dysfunction.

Official and local antimicrobial policies should be taken into account when the veterinary medicinal product is used.

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.

Whenever possible, fluoroquinolones should only be used based on susceptibility testing.

Use of the veterinary medicinal product deviating from the instructions given in the 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.

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

The veterinary medicinal product is an alkaline solution. Wash any splashes from skin or eyes immediately with water.

Do not eat, drink or smoke whilst using 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.

Direct contact with the skin should be avoided because of sensitisation, contact dermatitis and possible hypersensitivity reactions. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.
People with known hypersensitivity to (fluoro)quinolones should avoid contact with the veterinary medicinal product.

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

3.6. Adverse events

Cattle and pigs:

Uncommon (1 to 10 animals / 1 000 animals treated):	Injection site reaction. Gastrointestinal disorder[1]
Rare (1 to 10 animals / 10 000 animals treated):	Anaphylactic reactions[2]

[1] In cattle.

[2] Following intravenous administration in cattle.

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

Antagonistic effects due to concurrent administration of bacteriostatic antimicrobial agents such as macrolides or 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: Intravenous or subcutaneous use.
Pigs: Intramuscular 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.
Normal sterile precautions should be taken.

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.

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 accidental overdose (lethargy, anorexia) there is no antidote and treatment should be symptomatic.
No signs of over dosage were observed in pigs following administration of the veterinary medicinal product at five times the recommended therapeutic dose.
Degenerative changes of articular cartilage were observed in calves treated orally with 30 mg enrofloxacin/kg bw during 14 days.

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:

Intravenous use:	Meat and offal: 5 days.
	Milk: 3 days.
Subcutaneous use:	Meat and offal: 12 days.

Milk: 4 days.

Pigs:

Meat and offal: 13 days.

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. 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.

4.3 Pharmacokinetics

Enrofloxacin possesses a high distribution volume. Tissue levels 2-3 higher than that found in the serum, have been demonstrated in laboratory animals and target species. Organs in which high levels can be expected are the lungs, liver, kidney, skin, bone and lymphatic system. Enrofloxacin also distributes into the cerebrospinal fluid, the aqueous humour and the foetus in pregnant animals.

After an intravenous dose of 5 mg enrofloxacin per kg bw to lactating dairy cattle, the total systemic exposure over the dosing interval of 24 h was at 7.1 mg*h/L. In cattle serum, approximately 30% of drug exposure (2.31 mg*h/L) consisted of ciprofloxacin, the active metabolite of enrofloxacin. The drug was well distributed into the body compartments (V_{enro} = 1.5 L/kg, V_{cipro} = 8.51 L/kg). Total body

clearance was 0.71 L/h/kg.

In milk, most of drug activity consisted of ciprofloxacin. Overall drug concentrations peaked at 4.1 mg/kg two hours after treatment. Overall drug exposure over 24 h was 22.1 mg*h/L. The actives were eliminated from milk with a mean exposure half-life of 2.8 h.

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: 2 years.

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

5.3. Special precautions for storage

Protect from light.
Do not freeze.

5.4. Nature and composition of immediate packaging

Type II Amber glass vials of 250 ml capacity closed with pink bromobutyl rubber stoppers and aluminium flip-off seals. One vial of 250 ml is available in a cardboard box.
Type II Amber glass vials of 100 ml capacity closed with grey bromobutyl rubber stoppers and aluminium flip-off seals. One vial of 100 ml is available in a cardboard box.

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

LABORATORIOS CALIER, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

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

10/2025

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).

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (LABEL ON VIAL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ROXACIN 100 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Enrofloxacin 100 mg/ml

3. TARGET SPECIES

Cattle and pigs

4. ROUTES OF ADMINISTRATION

Cattle: Intravenous or subcutaneous use.
Pigs: Intramuscular 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.

Read the package leaflet before use.

Normal sterile precautions should be taken.

5. WITHDRAWAL PERIODS

Withdrawal period:

Cattle:

i.v.: Meat and offal: 5 days.

Milk: 3 days.

s.c.: Meat and offal: 12 days.

Milk: 4 days.

Pigs: Meat and offal: 13 days.

6. EXPIRY DATE

EXP: MM/YYYY
Shelf-life after first opening of the immediate packaging: 28 days.
Once broached, use by:

7. SPECIAL STORAGE PRECAUTIONS

Protect from light.
Do not freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Calier S.A.

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
CARDBOARD CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ROXACIN 100 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Enrofloxacin 100 mg/ml

3. PACKAGE SIZE

1 x 100 ml
1 x 250 ml

4. TARGET SPECIES

Cattle and pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle: Intravenous or subcutaneous use.

Pigs: Intramuscular 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.

Normal sterile precautions should be taken.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle:
i.v.: Meat and offal: 5 days.
Milk: 3 days.
s.c.: Meat and offal: 12 days.
Milk: 4 days.

Pigs: Meat and offal: 13 days.

8. EXPIRY DATE

Exp: MM/YYYY
Shelf-life after first opening of the immediate packaging: 28 days.
Once opened, use by:

9. SPECIAL STORAGE PRECAUTIONS

Protect from light.
Do not freeze.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Calier, S.A.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

ROXACIN 100 mg/ml solution for injection for cattle and pigs

2. Composition

Each ml contains:

Active substance:
Enrofloxacin……. 100 mg

Excipients:
Benzyl alcohol (E1519) ……. 7.8 mg
Disodium edetate……. 10.0 mg

Clear slightly yellowish solution

3. Target species

Cattle and pigs.

4. Indications for use

Treatment of bacterial infections caused by strains susceptible to enrofloxacin.

Cattle:

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mannheimia haemolytica* and *Mycoplasma* spp.

Treatment of acute severe mastitis caused by enrofloxacin susceptible strains of Escherichia coli.

Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.

Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*. Treatment of acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis* in cattle less than 2 years old.

Pigs:

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of Pasteurella multocida, Mycoplasma spp. and Actinobacillus pleuropneumoniae.

Treatment of infections of the urinary tract caused by enrofloxacin susceptible strains of

Escherichia coli.

Treatment of post-partum dysgalactiae syndrome, PDS (MMA syndrome) caused by enrofloxacin susceptible strains of Escherichia coli and Klebsiella spp.

Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of Escherichia coli.

Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.

5. Contraindications

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 for prophylaxis.
Do not use in known cases of resistance against other fluoroquinolone due to the potential for cross-resistance.

6. Special warnings

Special precautions for safe use in the target species:
The safety of the veterinary medicinal product has not been established in pigs or calves when administered by the intravenous route and use of this route of administration is not recommended in these animal groups.
Do not exceed the recommended dose.
Repeat injections should be administered at different sites.
Enrofloxacin should be used with caution in epileptic animals or animals affected by renal dysfunction.
Degenerative changes of articular cartilage were observed in calves treated orally with 30 mg enrofloxacin/kg bw during 14 days.
Official and local antimicrobial policies should be taken into account when the veterinary medicinal product is used.
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.

Whenever possible, fluoroquinolones should only be used based on susceptibility testing.
Use of the veterinary medicinal product deviating from the instructions given in the package leaflet 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The veterinary medicinal product is an alkaline solution. Wash any splashes from skin or eyes immediately with water.
Do not eat, drink or smoke whilst using 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 label to the physician.
Direct contact with the skin should be avoided because of sensitisation, contact dermatitis and possible hypersensitivity reactions. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.

People with known hypersensitivity to (fluoro)quinolones should avoid contact with the veterinary medicinal product.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Antagonistic effects due to concurrent administration of bacteriostatic antimicrobial agents such as macrolides or tetracyclines may occur. Enrofloxacin may interfere with the metabolism of theophylline, decreasing theophylline clearance resulting in increased plasma levels of theophylline.

Overdose:

In accidental overdose (lethargy, anorexia) there is no antidote and treatment should be symptomatic. No signs of over dosage were observed in pigs following administration of the veterinary medicinal product at five times the recommended therapeutic dose.

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

Major incompatibilities:

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

7. Adverse events

Cattle and pigs:

Uncommon (1 to 10 animals / 1 000 animals treated):	Injection site reaction. Gastrointestinal disorder[1]
Rare (1 to 10 animals / 10 000 animals treated):	Anaphylactic reactions[2]

[1] In cattle.
[2] Following intravenous administration in cattle.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Cattle: Intravenous (**i.v.**) or subcutaneous (**s.c.**) use.
Pigs: Intramuscular 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.
Normal sterile precautions should be taken.

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.

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.

9. Advice on correct administration

To ensure a correct dosage body weight should be determined as accurately as possible.
Normal sterile precautions should be taken.
The vial stopper may be broached a maximum of 20 times.

10. Withdrawal periods

Cattle:

Intravenous use:	Meat and offal: 5 days.
	Milk: 3 days.
Subcutaneous use:	Meat and offal: 12 days.
	Milk: 4 days.

Pigs:
Meat and offal: 13 days.

11. Special storage precautions

Keep out of the sight and reach of children.
Protect from light.
Do not freeze.
Do not use after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.
Shelf-life after first opening the immediate packaging: 28 days.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. 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).

14. Marketing authorization numbers and pack sizes

Box with 1 vial of 100 ml
Box with 1 vial of 250 ml

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

10/2025

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

16. Contact details

Marketing authorisation holder <and manufacturer responsible for batch release> <and contact details to report suspected adverse events>:

LABORATORIOS CALIER, S.A. [BE, DE, EL, ES, HR, HU, IE, IT, NL, PL, RO]
Calle Barcelonés 26
Polígono Industrial del Ramassà
08520 Les Franqueses del Vallès
Barcelona, Spain
Tel.: +34 (0) 938495133
pharmacovigilance@calier.es

CALIER PORTUGAL, S.A. [PT]
Centro Empresarial Sintra-Estoril II
Rua Pé de Mouro, Edifício
C Estrada de Albarraque
2710 - 335 Sintra 5
Portugal
Telf: +351 219248140
farmacovigilancia@calier.pt

Manufacturer responsible for batch release:
LABORATORIOS CALIER S.A.
C. Barcelonès, 26
Polígono Industrial del Ramassà
08520 Les Franqueses del Vallès
Barcelona. Spain

Local representatives and contact details to report suspected adverse events:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder listed below.