1. NAME OF THE VETERINARY MEDICINAL PRODUCT

KARIFLOX 25 mg/ml oral solution for calves

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Enrofloxacin .....25.0 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 (E-1519)	14.0 mg
Potassium hydroxide (for pH adjustment)	
Hypromellose	
Purified water	

Aqueous clear, oral solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (calves).

3.2. Indications for use for each target species

In cattle (calves):
- treatment of respiratory infections due to *Pasteurella multocida* and *Mannheimia haemolytica.*
- treatment of gastro-intestinal infection due to *Escherichia coli*.

To be used where clinical experience and/or sensitivity testing indicates enrofloxacin as the drug of choice.

3.3. Contraindications

Do not use when resistance/cross-resistance to (fluoro)quinolones is known to occur.
Do not use in cases of hypersensitivity to the active substance, other (flouro)quinolones or to any of the excipients.
Do not use in cases of disturbances in growth of cartilage and/or during injury of locomotory system particularly on functionally loaded joints or due to body weight loaded joints.
Do not use for prophylaxis.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

During the period of rapid growth, enrofloxacin may affect articular cartilage.

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.

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

Use of the veterinary medicinal product deviating from instructions given in the SPC may increase the prevalence of bacteria resistant to fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.

If there is no clinical improvement within two to three days susceptibility testing should be repeated and therapy should be changed, if appropriate

Calves receiving roughage only should not be treated orally but by injection.

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

People with known hypersensitivity to (fluoro)quinolones should avoid contact with the veterinary medicinal product.
Personal protective equipment consisting of impervious gloves should be worn when handling the veterinary medicinal product.
Wash any splashes from skin or eyes immediately with water.

Wash hands and exposed skin after use.
Do not eat, drink or smoke whilst using the veterinary medicinal product.
Direct contact with the skin should be avoided because of sensitisation, contact dermatitis and possible hypersensitivity reactions.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle (calves):

Undetermined frequency (cannot be estimated from the available data):	Gastrointestinal disorder

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 immediate packaging for respective contact details.

3.7. Use during pregnancy, lactation or lay

Not applicable.

3.8. Interaction with other medicinal products and other forms of interaction

Concurrent administration of enrofloxacin with other antimicrobials, tetracyclines and macrolide antibiotics, may result in antagonistic effects.

Absorption of enrofloxacin may be reduced if the veterinary medicinal product is administered together with substances containing magnesium or aluminium.

Do not combine enrofloxacin with steroidal anti-inflammatory products.

3.9. Administration routes and dosage

In drinking water/milk use.

The dose rate is 5 mg enrofloxacin per kg bodyweight (10 ml per 50 kg) daily for 5 days.

The dilution should be made on a daily basis immediately prior to provision, preferably in a glass container.

If the veterinary medicinal product is to be given via the drinking water, concentrations of between 50 and 200 ppm should be considered as suitable working dilutions; concentrations in excess of 250 ppm should be avoided as precipitation may occur.

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

Administration of enrofloxacin to calves at a dose of 30 mg/kg bodyweight per day resulted in damage to articular cartilage.
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

Meat and offal: 11 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01MA90

4.2 Pharmacodynamics

Enrofloxacin is bactericidal in action with activity against a range of Gram-positive and Gram-negative bacteria and mycoplasmas. The mechanism of action of the quinolones is unique among antimicrobials – they act primarily to inhibit bacterial DNA gyrase, an enzyme responsible for controlling the supercoiling of bacterial DNA during replication. Resealing of the double-stranded helix is inhibited resulting in irreversible degradation of the chromosomal DNA. The fluoroquinolones also possess activity against bacteria in the stationary phase by an alteration of the permeability of the outer membrane phospholipid cell wall.

Resistances to fluoroquinolones occur primarily by alterations in bactericidal cell wall penetration. Permeability changes occurs either via decreased permeability of the hydrophilic pores or through alteration of the active transport (efflux) pump, thereby decreasing the intracellular content of fluoroquinolones.

4.3 Pharmacokinetics

The pharmacokinetics of enrofloxacin are such that oral and parenteral administration leads to similar serum levels. Enrofloxacin possesses a high distribution volume. Tissue levels 2 – 3 times higher than that found in the serum, have been demonstrated in target species. Organs in which high levels can be expected are the lungs, liver, kidney, bone and lymphatic system. Enrofloxacin also distributes into the cerebrospinal fluid, the aqueous humorand the foetus in pregnant animals.

The degree of metabolism depends on the species and ranges between 50-60%. Biotransformation at hepatic level of enrofloxacin results in the active metabolite ciprofloxacin. In general, metabolism is by hydroxylation and oxidation processes to oxofluoroquinolones. Other reactions that also occur are N-dealkylation and conjugation with glucoronic acid.

Excretion occurs by biliary and renal route, with excretion in the urine predominating.

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.
Shelf-life after dilution according to directions: 24 hours.

5.3. Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4. Nature and composition of immediate packaging

Container Material:	High density polyethylene bottles
Container Closure:	Polyethylene screw cap
Container Colour:	White
Container Volume:	250 ml (in a cardboard box), 500 ml, 1 litre, 5 litres
Dosing Device:	For all containers a 20 ml measuring device of polypropylene is included.

Not all pack size 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 KARIZOO, S.A.

7. MARKETING AUTHORISATION NUMBER

VPA10786/004/001

8. DATE OF FIRST AUTHORISATION

10/07/2009

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

28/08/2026

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).