Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

COLMYC 25 mg/ml ORAL SOLUTION for calves

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:	
Active substance:	
Enrofloxacin	25.0 mg
Excipients:	
Benzyl alcohol (E1519)	14.0 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution.
Clear yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Calves.

4.2 Indications for use, specifying the target species

In 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.

4.3 Contraindications

Do not use in cases of confirmed, or suspected, resistance to quinolones.
Do not use in cases of known hypersensitivity to the active substance, to other (fluoro)quinolones or to any of excipients.
Do not use in case 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Do not use for prophylaxis.
Official and local antimicrobial policies should be taken into account when the 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 be used based on susceptibility testing.

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

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

4.6 Adverse reactions (frequency and seriousness)

Gastrointestinal disturbances may occasionally occur.

4.7 Use during pregnancy, lactation or lay

Cattle: Not applicable. The product is not indicated for use in adult cattle.

4.8 Interaction with other medicinal products and other forms of interaction

Concurrent use of enrofloxacin with other antimicrobials, tetracyclines and macrolide antibiotics, may result in antagonistic effects.
Absorption of enrofloxacin may be reduced if the product is administered together with substances containing magnesium or aluminium.
Do not combine enrofloxacin with steroidal anti-inflammatory products.

4.9 Amounts to be administered and administration route

Calves: Administer via milk replacer, milk or electrolyte solution or drinking water.
The dose rate is 5 mg enrofloxacin per kg bodyweight (10 ml per 50 kg) daily for 5 days.
Medicated fluids should be made up immediately prior to provision on a daily basis.
The dilution should be made on a daily basis immediately prior to provision, preferably in a glass container.
If the product is to be given via milk/milk replacer or electrolyte solution, concentrations in excess of 100 ppm and 200 ppm, respectively, should be avoided as solubility in these media above these concentrations has not been demonstrated.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Do not exceed the recommended dose. In accidental overdose there is no antidote and treatment should be symptomatic.
Administration of enrofloxacin to calves at a dose of 30 mg/kg bodyweight per day resulted in damage to articular cartilage.

4.11 Withdrawal Period(s)

Calves: Meat and offal: 11 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, fluoroquinolones
ATCvet code: QJ01MA90

5.1 Pharmacodynamic properties

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*, *Pasteurella* spp. (e.g. *Pasteurella multocida*) 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.

5.2 Pharmacokinetic properties

The pharmacokinetics of enrofloxacin are such that both oral and parenteral administration leads to similar serum levels. Enrofloxacin possesses a high distribution volume. Tissue levels 2-3 times higher than 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.
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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Potassium hydroxide
Hypromellose
Purified water

6.2 Incompatibilities

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

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate packaging: 3 months
Shelf-life after dilution or reconstitution according to directions: 24 hours

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Container Material:	High density polyethylene bottles
Container Closure:	Green high density polyethylene screw cap
Container Colour:	White
Container Volumes:	100 ml, 500ml, 1L and 5L

Not all pack sizes may be marketed

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

SP VETERINARIA SA
Crta Reus Vinyols km 4.1
Riudoms (43330) - Spain

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10790/003/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th September 2010
Renewal of the last authorisation: 29th September 2015

10 DATE OF REVISION OF THE TEXT

December 2016