Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

KARIFLOX 5 mg/ml oral solution for piglets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Enrofloxacin..... 5.0 mg

Excipients:
Benzyl Alcohol (E 1519)..... 14.0 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution.
Ready to use aqueous clear, oral solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Piglets.

4.2 Indications for use, specifying the target species

In piglets (up to 10 kg):
- 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 when resistance/cross-resistance to (fluoro)quinolones is known to occur.
Do not use in case of known hypersensitivity to the active substance, other (flouro)quinolones or to any of the 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 only 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.

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

Those with known hypersensitivity to (fluoro)quinolones should avoid contact with this product.
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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not applicable.
The product is not indicated for use in adult pigs.

4.8 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 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

The contents of the product are administered orally using the dosing pump. 1 pump stroke delivers 1 ml.

Dosage:

1 ml of product (i.e. 5 mg Enrofloxacin) per 3 kg bodyweight daily for 3 to 5 days.

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

Discard the first pump stroke in order to assure the dosing accuracy.

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

Administration of enrofloxacin to piglets in overdose (50 mg/kg bodyweight per day) has been reported to result in histopathological evidence of arthropathy.
Do not exceed the recommended dose. In accidental overdose there is no antidote and treatment should be symptomatic.

4.11 Withdrawal Period(s)

Meat and offal: 10 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: antibacterials for systemic use, fluoroquinolones, enrofloxacin.
ATCvet code: QJ01MA90

5.1 Pharmacodynamic properties

Enrofloxacin is a synthetic, broad spectrum antimicrobial substance, belonging to the fluoroquinolone group of antibiotics. It 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.

5.2 Pharmacokinetic properties

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E 1519)
Potassium hydroxide (for pH adjustment)
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: 2 years
Shelf-life after first opening the immediate packaging: 28 days

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:	Polypropylene screw cap
Container Colour:	White
Container Volume:	250 ml
Dosing Device:	Polypropylene/polyethylene/stainless steel pump dispensing 1 ml

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

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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10786/003/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10th July 2009 - 9th July 2014

10 DATE OF REVISION OF THE TEXT