Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Reneval 50 mg/ml Solution for Injection for cattle, pigs, dogs and cats.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of solution contains:

Active substance:

Enrofloxacin	50.0 mg

Excipients:

n-Butanol	30.0 mg

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.
Clear light yellow solution free from particulate matter.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, Pigs, Dogs and Cats.

4.2 Indications for use, specifying the target species

Cattle:
Diseases of the respiratory and alimentary tract of bacterial or mycoplasmal origin (e.g. *pasteurellosis, mycoplasmosis, coli-bacillosis, coli-septicaemia and* salmonellosis) and secondary bacterial infections subsequent to viral conditions (e.g. viral pneumonia), where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

Pigs:
Diseases of the respiratory and alimentary tract of bacterial or mycoplasmal origin (e.g. *pasteurellosis, actinobacillosis, mycoplasmosis, coli-bacillosis, coli-septicaemia* and salmonellosis) and multifactorial diseases such as atrophic rhinitis and enzootic pneumonia, where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

Dogs and Cats:
Treatment of bacterial infections of the alimentary, respiratory and urogenital tracts, skin, secondary wound infections and otitis externa where clinical experience, supported where possible by sensitivity testing of the causal organism, 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 the case of known hypersensitivity to fluoroquinolones or to any of the excipients.
Do not use in young dogs during their period of rapid growth, i.e. in small breeds of dogs less than 8 months of age, in big breeds of dogs less than 12 months of age, in giant breeds of dogs less than 18 months of age.
Do not use in animals that are epileptic or suffer from seizures since enrofloxacin may cause CNS stimulation.
Not for use in cats less than 8 weeks of age.
The product should not be used for prophylaxis.
Do not use in horses.

4.4 Special warnings for each target species

Cattle, pigs:
None.
Cats:
Retinotoxic effects including blindness can occur when the recommended dose is exceeded.
Dogs:
Occasionally skin reactions have been seen after administration to kennelled greyhounds.

4.5 Special precautions for use

i) Special precautions for use in animals

Do not exceed the recommended dosage.

Repeat injections should be made at different sites.

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

Use of the 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.

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

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

The product is an alkaline solution.

People with known hypersensitivity to (fluoro)quinolones should avoid contact with this product. Avoid direct contact with skin and eyes when handling the product to prevent sensitisation and contact dermatitis. Wash any splashes from skin and eyes immediately with water.

Do not eat, drink or smoke whilst handling the product.

Care should be taken to avoid accidental self-injection. If accidental injection occurs, seek medical advice immediately.

iii) Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

Local tissue reactions may occur at the injection site.

In cattle and dogs, gastrointestinal disturbances may occasionally occur.

4.7 Use during pregnancy, lactation or lay

There is no restriction on the use of this product during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Combination of enrofloxacin with cloramphenicol, macrolide antibiotics or tetracyclines may produce antagonistic effects.

Enrofloxacin may interfere with the metabolism of theophylline, decreasing theophylline clearance resulting in increased plasma levels of theophylline.

4.9 Amounts to be administered and administration route

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

Cattle:
2.5 mg enrofloxacin per kg bodyweight (0.5ml/10 kg) daily by subcutaneous injection for 3 days. This rate may be doubled to 5 mg enrofloxacin per kg bodyweight (1.0 ml/10 kg) for 5 days for salmonellosis and complicated respiratory diseases.

Not more than 10 ml should be administered at the one subcutaneous injection site.

Pigs:
2.5 mg enrofloxacin per kg bodyweight (0.5 ml/10 kg) daily by intramuscular injection for 3 days. This rate may be doubled to 5 mg enrofloxacin per kg bodyweight (1.0 ml/10 kg) for 5 days for salmonellosis and complicated respiratory diseases.
Not more than 2.5 ml should be administered at the one intramuscular site.

Dogs and Cats:
5mg enrofloxacin per kg bodyweight (1.0 ml/10 kg) daily by subcutaneous injection once daily for up to 5 days.

Maximum number of piercings is 48 for the 100 ml stopper and 60 for the 250 ml stopper.

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. No signs of over dosage were observed in pigs following administration of the product at five times the recommended therapeutic dose.
In target animal studies, cats have been shown to suffer ocular damage after receiving doses of more than 15 mg/kg once daily for 21 consecutive days. Doses of 30 mg/kg given once daily for 21 consecutive days have been shown to cause irreversible ocular damage. At 50 mg/kg given once daily for 21 consecutive days, blindness can occur.

4.11 Withdrawal Period(s)

Cattle:
Meat and offal: 14 days
Milk: Not to be used in animals producing milk for human consumption.
Pig:
Meat and offal: 10 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinfectives for systemic use, fluoroquinolones.
ATCvet-Code: QJ01MA90

5.1 Pharmacodynamic properties

Enrofloxacin exerts bactericidal activity concentration-dependant with similar values of minimal inhibit concentration and minimal bactericide concentrations. It also possesses activity against bacteria in the stationary phase by an alteration of the permeability of the outer membrane phospholipid cell wall.
Induction of resistance against quinolones can develop by mutations in the gyrase gene of bacteria and by changes in cell permeability towards quinolones.

5.2 Pharmacokinetic properties

The pharmacokinetics of enrofloxacin in dogs and cats 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 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

n-Butanol
Potassium hydroxide (for pH adjustment)
Water for injections

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: 36 months

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

6.4 Special precautions for storage

Do not freeze.
Bottles should remain upright during storage.

6.5 Nature and composition of immediate packaging

Container material: Amber Glass Type I
Container closure: Grey teflonised chlorobutyl rubber stopper with an aluminium cap
Container volumes: 100ml, 250ml

No of containers in a carton:
1 x 100 ml, 5 x 100 ml, 10 x 100 ml, 12 x 100 ml, 15 x 100 ml, 20 x 100 ml
1 x 250 ml, 5 x 250 ml, 10 x 250 ml, 12 x 250 ml, 15 x 250 ml, 20 x 250 ml.

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 material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Pfizer Healthcare Ireland
Trading as: Pfizer Animal Health,
Ringaskiddy,
Co. Cork,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10019/193/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th March 2012

10 DATE OF REVISION OF THE TEXT