

# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Reneval 100 mg/ml Solution for Injection for cattle and pigs.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of solution contains:

### Active substances:

Enrofloxacin	100.0 mg
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### Excipients:

n-Butanol	30.0 mg
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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 and pigs.

### 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 infections (e.g. viral pneumonia) where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

Treatment of local signs (inflammation, milk quality and yield) associated with peracute/acute mastitis in lactating dairy cattle caused by *E. coli*, where herd history and previous sensitivity testing indicate enrofloxacin as the drug of choice.

#### *Pigs*

Diseases of the respiratory and alimentary tract of bacterial or mycoplasmal origin (e.g. *pasteurellosis*, *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.

### **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.

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

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 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

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. The product is an alkaline solution. Wash any splashes from skin or 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 self injection occurs seek medical advice immediately.

### iii) Other precautions

None known.

## 4.6 Adverse reactions (frequency and seriousness)

Local tissue reactions may occasionally occur at the injection site.

In cattle, 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 chloramphenicol, 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 correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

##### *Cattle:*

For respiratory and alimentary infections in cattle and secondary bacterial infections: administer by subcutaneous injection.

- 2.5 mg enrofloxacin per kg bodyweight) daily by subcutaneous injection for 3 days (2.5 ml per 100 kg bodyweight). This rate may be doubled to 5 mg/kg bodyweight (5 ml per 100 kg) for 5 days for salmonellosis and complicated respiratory disease.

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

For *E. coli* mastitis: administer by slow intravenous injection.

- 5.0 ml per 100 kg bodyweight (5 mg enrofloxacin per kg bodyweight) daily for 2 days.

##### *Pigs:*

For respiratory and alimentary infections in pigs and secondary bacterial infections: administer by intramuscular injection.

2.5 mg enrofloxacin per kg bodyweight) daily by intramuscular injection for 3 days (2.5 ml per 100 kg bodyweight). This rate may be doubled to 5 mg/kg bodyweight (5 ml per 100 kg) for 5 days for salmonellosis and complicated respiratory disease.

Not more than 2.5 ml should be administered at any one intramuscular injection site in store pigs or 5 ml at any one intramuscular injection site in sows.

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.

## 4.11 Withdrawal Period(s)

### Cattle : Subcutaneous Use

Meat and offal:	10 days
Milk:	84 hours (7 milkings)

### Cattle: Intravenous Use

Meat and offal:	4 days.
Milk:	72 hours (6 milkings).

### Pigs: Intramuscular Use

Meat and offal:	10 days.
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## 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 are such that oral and parenteral administration leads to similar serum levels. 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 body weight (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 ( $V_{\text{enro}} = 1.5 \text{ L/kg}$ ,  $V_{\text{cipro}} = 8.51 \text{ L/kg}$ ). 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.

## **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: 10019/193/002

**9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

30th March 2012

**10 DATE OF REVISION OF THE TEXT**