

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

ENRODEXIL 100 mg/ml solution for injection for cattle and pigs

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 1 ml of solution contains:

**Active substance:**

Enrofloxacin 100.0 mg

**Excipients:**

Benzyl alcohol (E 1519) 7.8 mg

Disodium edetate 10.0 mg

For the full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Solution for injection

Clear slightly yellowish solution

### **4. CLINICAL PARTICULARS**

#### **4.1. Target species**

Cattle and pigs.

#### **4.2. Indications for use, specifying the target species**

##### **Cattle**

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida*, *Mannheimia haemolytica* and *Mycoplasma spp.*

Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.

Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.

Treatment of acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis* in cattle less than 2 years old.

##### **Pigs**

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida*, *Mycoplasma spp.* and *Actinobacillus pleuropneumoniae*.

Treatment of infections of the urinary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.

Treatment of post-partum dysgalactiae syndrome, PDS (MMA syndrome) caused by enrofloxacin susceptible strains of *Escherichia coli* and *Klebsiella spp.*

Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.

Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.

Enrofloxacin should be used 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 for prophylaxis.

Do not use when resistance / cross resistance to (Fluoro)quinolones is known to occur.

Refer to section 4.5.

Do not use in case of known hypersensitivity to fluoroquinolones or to any of the excipients.

Do not use in growing horses because of possible deleterious damage on articular cartilage.

### **4.4. Special warnings, for each target species**

None

### **4.5. Special precautions for use**

#### Special precautions for use in animals

Do not exceed the recommended dose.

Repeat injections should be administered at different sites.

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

Degenerative changes of articular cartilage were observed in calves treated orally with 30 mg enrofloxacin/kg bw during 14 days.

The use of enrofloxacin in growing lambs at the recommended dose for 15 days caused histological changes in the articular cartilage, not associated with clinical signs.

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.

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

The product is an alkaline solution. Wash any splashes from skin or eyes immediately with water.

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

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

Direct contact with the skin should be avoided because of sensitisation, contact dermatitis and possible hypersensitivity reactions. Wear gloves.

#### **4.6. Adverse reactions (frequency and seriousness)**

Local tissue reactions may occasionally occur at the injection site. Normal sterile precautions should be taken.

In cattle, gastrointestinal disturbances may occasionally occur.

#### **4.7. Use during pregnancy, lactation or lay**

Can be used during pregnancy and lactation.

#### **4.8. Interaction with other medicinal products and other forms of interaction**

Antagonistic effects due to concurrent administration of macrolides, and tetracyclines may occur. 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**

Intravenous, subcutaneous or intramuscular use.

Repeated injections should be made at different injection sites.

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

##### **Cattle:**

5 mg of enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, once daily for 3-5 days.

Acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis* in cattle less than 2 years old: 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, once daily for 5 days.

The product can be administered by slow intravenous or subcutaneous administration.

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

##### **Pigs:**

2.5 mg of enrofloxacin/kg bw, corresponding to 0.5 ml/20 kg bw, once daily by intramuscular injection for 3 days.

Alimentary tract infection or septicaemia caused by *Escherichia coli*: 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, once daily by intramuscular injection for 3 days.

In pigs, the injection should be made in the neck at the ear base.

Not more than 3 ml should be administered at one intramuscular injection site.

The stopper should not be punctured more than 20 times.

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

Do not exceed the recommended dose.

In accidental overdose (lethargy, anorexia) 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 periods

##### Cattle:

Following intravenous injection:

Meat and offal: 5 days.

Milk: 3 days.

Following subcutaneous injection:

Meat and offal: 12 days

Milk: 4 days

##### Pigs:

Meat and offal: 13 days

### 5. PHARMACOLOGICAL 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*, *Klebsiella spp.*, *Actinobacillus pleuropneumoniae*, *Mannheimia haemolytica*, *Pasteurella spp.* (e.g. *Pasteurella multocida*), against Gram-positive bacteria such as *Staphylococcus spp.* (e.g. *Staphylococcus aureus*) and against *Mycoplasma spp.* 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 particulars**

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.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1. List of excipients**

Benzyl alcohol (E 1519)  
Disodium edetate  
Potassium hydroxide (for pH adjustment)  
Glacial acetic acid  
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: 2 years.  
Shelf life after first opening the immediate packaging: 28 days.

### **6.4. Special precautions for storage**

Protect from light.  
Do not freeze.

### **6.5. Nature and composition of the immediate packaging**

Type II Amber glass vials of 250 ml capacity closed with pink bromobutyl rubber stoppers and aluminium flip-off seals. One vial of 250 ml is available in a cardboard box.  
Type II Amber glass vials of 100 ml capacity closed with grey bromobutyl rubber stoppers and aluminium flip-off seals. One vial of 100 ml is available in a cardboard box.  
Not all pack sizes may be marketed

**6.6. Special precautions for the disposal of unused veterinary medicinal product or waste derived from the use of such products.**

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

**7. MARKETING AUTHORISATION HOLDER**

Industrial Veterinaria, S.A.  
Esmeralda, 19  
E - 08950 Esplugues de Llobregat  
Barcelona  
Spain

**8. MARKETING AUTHORISATION NUMBER**

Vm 36547/4003

**9. DATE OF FIRST AUTHORISATION**

20 April 2011

**10. DATE OF REVISION OF THE TEXT**

May 2016

**PROHIBITION OF SALE, SUPPLY AND/OR USE**

Not applicable

Approved: 18 May 2016

A handwritten signature in black ink, consisting of a stylized, cursive 'R' followed by a vertical line and a small flourish at the bottom.