

## **ANNEX I**

### **SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrotron 100, 100 mg/ml solution for injection for cattle, sheep, goats and pigs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

### Active substance:

Enrofloxacin 100.0 mg

### Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
1-Butanol	30.0 mg
Potassium hydroxide	
Hydrochloric acid, dilute	
Water for Injections	

Clear, slightly yellowish to yellowish orange solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cattle, Sheep, Goats, Pigs

### 3.2 Indications for use for each 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 acute severe mastitis caused by enrofloxacin susceptible strains of *Escherichia coli*.

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.

#### Sheep

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 mastitis caused by enrofloxacin susceptible strains of *Staphylococcus aureus* and *Escherichia coli*.

#### Goats

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

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 mastitis caused by enrofloxacin susceptible strains of *Staphylococcus aureus* and *Escherichia coli*.

### **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*.

## **3.3 Contraindications**

Do not use in cases of hypersensitivity to the active substance or other fluoroquinolones or to any of the excipients.

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

## **3.4 Special warnings**

None.

## **3.5 Special precautions for use**

Special precautions for safe use in the target species:

Official and local antimicrobial policies should be taken into account when the veterinary medicinal 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 veterinary medicinal product including use deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to enrofloxacin and may decrease the effectiveness of treatment with all fluoroquinolones due to the potential for cross resistance.

Degenerative changes of articular cartilage were observed in calves treated orally with 30 mg enrofloxacin/kg body weight 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.

In countries where feeding of fallen stock to scavenger bird populations is permitted as a conservation measure (see Commission Decision 2003/322/EC), the possible risk to hatching success should be considered before feeding carcasses of livestock recently treated with this veterinary medicinal product.

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

People with known hypersensitivity to fluoroquinolones should avoid any contact with the veterinary medicinal product.

Avoid skin and eye contact. Wash any splashes from skin or eyes immediately with water.

Wash hands after use. Do not eat, drink or smoke whilst handling the veterinary medicinal product.

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

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Cattle, sheep, goats, pigs:

Very rare ( $<1$ animal / 10,000 animals treated, including isolated reports):	Shock <sup>1</sup> Digestive tract disorder (such as diarrhoea) <sup>2</sup>
Undetermined frequency, (cannot be estimated from the available data):	Injection site inflammation <sup>3</sup>

<sup>1</sup> In cattle after intravenous administration, presumably as a result of circulatory impairment.

<sup>2</sup> Generally mild and transient.

<sup>3</sup> In pigs, after intramuscular administration, may persist up to 28 days after the injection.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

#### Cattle

The safety of the veterinary medicinal product has been established in pregnant cows during the 1st quarter of pregnancy. The veterinary medicinal product can be used in pregnant cows during the 1st quarter of pregnancy.

The use of the veterinary medicinal product in cows during the 3 last quarters of pregnancy should be based on a benefit-risk assessment by the responsible veterinarian.

The veterinary medicinal product can be used in cows during lactation.

#### Sheep and goats

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit-risk assessment by the responsible veterinarian.

#### Pigs

The safety of the veterinary medicinal product has not been established during pregnancy. Use only according to the benefit-risk assessment by the responsible veterinarian.

The veterinary medicinal product can be used in sows during lactation.

### 3.8 Interaction with other medicinal products and other forms of interaction

Do not use enrofloxacin concomitantly with antimicrobial substances acting antagonistically to quinolones (e.g. macrolides, tetracyclines or phenicols).

Do not use concurrently with theophylline as the elimination of theophylline may be delayed.

### 3.9 Administration routes and dosage

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.

### **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 veterinary medicinal product can be administered by slow intravenous or subcutaneous administration.

Acute mastitis caused by *Escherichia coli*: 5 mg enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, by slow intravenous injection once daily for two consecutive days.

The second dose may be administered by the subcutaneous route. In this case, the withdrawal period following subcutaneous injection applies.

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

### **Sheep and goats**

5 mg of enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, once daily by subcutaneous injection for 3 days. Not more than 6 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 may be safely punctured up to 125 times. For multiple vial entry, an aspirating needle or multi-dose syringe is recommended to avoid excessive broaching of the stopper.

### **3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)**

In cases of accidental overdoses digestive tract disorders (e.g. vomiting, diarrhoea) and neurological disorders may occur.

In pigs, no adverse effects were reported after the administration of 5 times the recommended dose.

In cattle, sheep and goat, overdose has not been documented.

In accidental overdose there is no antidote and treatment should be symptomatic.

### **3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance**

Not applicable.

### **3.12 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.

Sheep:

Meat and offal: 4 days.

Milk: 3 days.

Goats:

Meat and offal: 6 days.

Milk: 4 days.

Pigs:

Meat and offal: 13 days.

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code:

QJ01MA90

### 4.2 Pharmacodynamics

#### 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.

### 4.3 Pharmacokinetics

Enrofloxacin is rapidly absorbed after parenteral injection. Bioavailability is high (approximately 100% in pig and cattle) with a low to moderate plasma protein binding (approximately 20 to 50%). Enrofloxacin is metabolized to the active substance ciprofloxacin at approximately 40% in ruminants and less than 10% in pigs.

Enrofloxacin and ciprofloxacin distribute well into all target tissues, e.g. lung, kidney, skin and liver, reaching 2- to 3-fold higher concentrations than in plasma. Parent substance and active metabolite are cleared from the body via urine and faeces.

Accumulation in plasma does not occur following a treatment interval of 24 h.

In milk, most of drug activity consists on ciprofloxacin. Overall drug concentrations peak at 2 hours after treatment showing an approximately 3-fold higher total exposure over the 24 hours dosing interval compared to plasma.

	Pigs	Pigs	Cattle	Cattle
Dose rate (mg/kg bw)	2.5	5	5	5
Route of administration	im	im	iv	sc
T <sub>max</sub> (h)	2	2	-	3.5
C <sub>max</sub> (µg/ml)	0.7	1.6	-	0.733

AUC (µg x h/ml)	6.6	15.9	9.8	5.9
Terminal half-life (h)	13.12	8.10	-	7.8
Elimination half-life (h)	7.73	7.73	2.3	-
F (%)	95.6	-	-	88.2

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

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

### **5.2 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

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

### **5.3 Special precautions for storage**

Keep the vial in the outer carton in order to protect from light.

### **5.4 Nature and composition of immediate packaging**

Clear glass vial type I with siliconised, teflonised chlorobutyl, or siliconised, uncoated bromobutyl rubber stopper, sealed with an aluminium cap in a cardboard box.

Pack sizes:

1 x 100 ml

12 x 100 ml

1 x 250 ml

12 x 250 ml

Not all pack sizes may be marketed.

### **5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products**

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

## **6. NAME OF THE MARKETING AUTHORISATION HOLDER**

aniMedica GmbH

## **7. MARKETING AUTHORISATION NUMBER(S)**

## **8. DATE OF FIRST AUTHORISATION**

Date of first authorisation:

## **9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

## **10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database](https://medicines.health.europa.eu/veterinary) (<https://medicines.health.europa.eu/veterinary>).



**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE****CARTON****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Enrotron 100, 100 mg/ml solution for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

**Active Substance**

Enrofloxacin	100.0 mg
--------------	----------

**3. PACKAGE SIZE**

100 ml

12 x 100ml

250 ml

12 x 250 ml

**4. TARGET SPECIES**

Cattle, Sheep, Goats, Pigs

**5. INDICATIONS****6. ROUTES OF ADMINISTRATION**

Cattle: intravenous or subcutaneous use

Sheep, goats: subcutaneous use

Pigs: intramuscular use

**7. WITHDRAWAL PERIODS**

Withdrawal period:

Cattle:

IV:

Meat and offal: 5 days.

Milk: 3 days.

SC:

Meat and offal: 12 days.

Milk: 4 days.

Sheep:

Meat and offal: 4 days.

Milk: 3 days.

Goats:

Meat and offal: 6 days.

Milk: 4 days.

Pigs:

Meat and offal: 13 days.

<b>8. EXPIRY DATE</b>
-----------------------

Exp. {mm/yyyy}

Once broached use within 28 days.

Once broached use by.....

<b>9. SPECIAL STORAGE PRECAUTIONS</b>
---------------------------------------

Keep the vial in the outer carton in order to protect from light.

<b>10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”</b>
--

Read the package leaflet before use.

<b>11. THE WORDS “FOR ANIMAL TREATMENT ONLY”</b>
--

For animal treatment only.

<b>12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”</b>
--

Keep out of the sight and reach of children.

<b>13. NAME OF THE MARKETING AUTHORISATION HOLDER</b>
---

aniMedica GmbH

<b>14. MARKETING AUTHORISATION NUMBERS</b>
--

<b>15. BATCH NUMBER</b>
-------------------------

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE****LABEL VIAL****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Enrotron 100, 100 mg/ml solution for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

**Active Substance**

Enrofloxacin 100.0 mg

**3. TARGET SPECIES**

Cattle, Sheep, Goats, Pigs

**4. ROUTES OF ADMINISTRATION**

Cattle: intravenous or subcutaneous use

Sheep, goats: subcutaneous use

Pigs: intramuscular use

Read the package leaflet before use.

**5. WITHDRAWAL PERIODS**

Withdrawal period:

Cattle:

IV:

Meat and offal: 5 days.

Milk: 3 days.

SC:

Meat and offal: 12 days.

Milk: 4 days.

Sheep:

Meat and offal: 4 days.

Milk: 3 days.

Goats:

Meat and offal: 6 days.

Milk: 4 days.

Pigs:

Meat and offal: 13 days.

**6. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached use within 28 days.

Once opened use by ....

<b>7. SPECIAL STORAGE PRECAUTIONS</b>
---------------------------------------

Keep the vial in the outer carton in order to protect from light.

<b>8. NAME OF THE MARKETING AUTHORISATION HOLDER</b>
--

aniMedica GmbH

<b>9. BATCH NUMBER</b>
------------------------

Lot {number}

## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Enrotron 100, 100 mg/ml solution for injection for cattle, sheep, goats and pigs

### 2. Composition

Each ml contains:

#### Active Substance

Enrofloxacin	100.0 mg
--------------	----------

#### Excipients

1-Butanol	30.0 mg
-----------	---------

Clear, slightly yellowish to yellowish orange solution.

### 3. Target species

Cattle, Sheep, Goats, Pigs

### 4. Indications for use

#### Cattle

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

Treatment of acute severe mastitis caused by enrofloxacin susceptible strains of *Escherichia coli*.

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.

#### Sheep

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 mastitis caused by enrofloxacin susceptible strains of *Staphylococcus aureus* and *Escherichia coli*.

#### Goats

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

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 mastitis caused by enrofloxacin susceptible strains of *Staphylococcus aureus* and *Escherichia coli*.

#### 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*.

## **5. Contraindications**

Do not use in cases of hypersensitivity to the active substance or other fluoroquinolones or to any of the excipients.

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

## **6. Special warnings**

Special precautions for safe use in the target species:

Official and local antimicrobial policies should be taken into account when the veterinary medicinal 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 veterinary medicinal product including use deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to enrofloxacin and may decrease the effectiveness of treatment with all fluoroquinolones due to the potential for cross resistance.

Degenerative changes of articular cartilage were observed in calves treated orally with 30 mg enrofloxacin/kg body weight 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.

In countries where feeding of fallen stock to scavenger bird populations is permitted as a conservation measure (see Commission Decision 2003/322/EC), the possible risk to hatching success should be considered before feeding carcasses of livestock recently treated with this veterinary medicinal product.

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

People with known hypersensitivity to fluoroquinolones should avoid any contact with the veterinary medicinal product.

Avoid skin and eye contact. Wash any splashes from skin or eyes immediately with water.

Wash hands after use. Do not eat, drink or smoke whilst handling the veterinary medicinal product.

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

Pregnancy and lactation:

Cattle

The safety of the veterinary medicinal product has been established in pregnant cows during the 1st quarter of pregnancy. The veterinary medicinal product can be used in pregnant cows during the 1st quarter of pregnancy.

The use of the veterinary medicinal product in cows during the 3 last quarters of pregnancy should be based on a benefit-risk assessment by the responsible veterinarian.

The veterinary medicinal product can be used in cows during lactation.

Sheep and goats

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit-risk assessment by the responsible veterinarian.

## Pigs

The safety of the veterinary medicinal product has not been established during pregnancy. Use only according to the benefit-risk assessment by the responsible veterinarian.

The veterinary medicinal product can be used in sows during lactation.

### Interaction with other medicinal products and other forms of interaction:

Do not use enrofloxacin concomitantly with antimicrobial substances acting antagonistically to quinolones (e.g. macrolides, tetracyclines or phenicols).

Do not use concurrently with theophylline as the elimination of theophylline may be delayed.

### Overdose:

In cases of accidental overdoses digestive tract disorders (e.g. vomiting, diarrhoea) and neurological disorders may occur.

In pigs, no adverse effects were reported after the administration of 5 times the recommended dose.

In cattle, sheep and goat, overdose has not been documented.

In accidental overdose there is no antidote and treatment should be symptomatic.

### Major incompatibilities:

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

## **7. Adverse events**

Cattle, sheep, goats, pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):

Shock<sup>1</sup>

Digestive tract disorder (such as diarrhoea)<sup>2</sup>

Undetermined frequency, (cannot be estimated from the available data):

Injection site inflammation<sup>3</sup>

<sup>1</sup> In cattle after intravenous administration, presumably as a result of circulatory impairment.

<sup>2</sup> Generally mild and transient.

<sup>3</sup> In pigs, after intramuscular administration, may persist up to 28 days after the injection.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

## **8. Dosage for each species, routes and method of administration**

Intravenous, subcutaneous or intramuscular use.

Repeated injections should be made at different injection sites.

### Cattle

5 mg of enrofloxacin/kg body weight (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 veterinary medicinal product can be administered by slow intravenous or subcutaneous administration.

Acute mastitis caused by *Escherichia coli*: 5 mg enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, by slow intravenous injection once daily for two consecutive days.

The second dose may be administered by the subcutaneous route. In this case, the withdrawal period following subcutaneous injection applies.

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

### **Sheep and goats**

5 mg of enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, once daily by subcutaneous injection for 3 days. Not more than 6 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 1.0 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 may be safely punctured up to 125 times. For multiple vial entry, an aspirating needle or multi-dose syringe is recommended to avoid excessive broaching of the stopper.

## **9. Advice on correct administration**

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

## **10. 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.

### **Sheep:**

Meat and offal: 4 days.

Milk: 3 days.

### **Goats:**

Meat and offal: 6 days.

Milk: 4 days

### **Pigs:**

Meat and offal: 13 days.

## **11. Special storage precautions**

Keep out of the sight and reach of children.

Keep the vial in the outer carton in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on carton and vial after Exp. The expiry date refers to the last day of that month.

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

## **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## **14. Marketing authorisation numbers and pack sizes**

XXXXXXX

Pack sizes:

1 x 100 ml

12 x 100 ml

1 x 250 ml

12 x 250 ml

Not all pack sizes may be marketed.

## **15. Date on which the package leaflet was last revised**

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

## **16. Contact details**

Marketing authorisation holder and contact details to report suspected adverse reactions:

aniMedica GmbH

Im Südfeld 9

48308 Senden-Bösensell

Germany

Tel:+49-2536-3302-0

Manufacturer responsible for batch release:

aniMedica GmbH

Im Südfeld 9

48308 Senden-Bösensell

Germany

Industrial Veterinaria S.A.

C/Esmeralda 19  
08950 Esplugues de Llobregat (Barcelona)  
Spain

Local representatives and contact details to report suspected adverse reactions: