

*[Version 9.1, 11/2024]*

## **ANNEX I**

### **SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril One 100 mg/ml solution for injection for cattle and pig (AT, CY, CZ, EL, PT, PL, SK)

Baytril uno 100 mg/ml solution for injection for cattle and pig (ES)

Baytril Max 100 mg/ml solution for injection for cattle and pig (BG, HR, SI)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

### Active substance:

Enrofloxacin 100 mg

### Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
n- Butanol	30 mg
Benzyl alcohol (E1519)	20 mg
Arginine	
Water for injections	

Clear, yellow solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cattle, Pigs.

### 3.2 Indications for use for each target species

#### Cattle:

For the treatment of respiratory tract infections caused by *Histophilus somni*, *Mannheimia haemolytica*, *Pasteurella multocida* and *Mycoplasma* spp.

For the treatment of mastitis caused by *E. coli*.

#### Pigs:

For the treatment of bacterial bronchopneumonia caused by *Actinobacillus pleuropneumoniae*, *Haemophilus parasuis* and *Pasteurella multocida*.

### 3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, other (fluoro)quinolones or to any of the excipients.

Do not use in animals with central nervous system-associated seizure disorders, existing impairment of cartilage growth or damage to the locomotor apparatus involving joints subjected to heavy functional stresses or load-bearing joints.

### 3.4 Special warnings

Cross-resistance has been shown between enrofloxacin and other (fluoro)quinolones in target pathogens, e.g. *Escherichia coli*. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to fluoroquinolones because its effectiveness may be reduced.

### **3.5 Special precautions for use**

#### Special precautions for safe use in the target species:

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach. Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

The veterinary medicinal product should only be used in individual animals

The feeding of waste milk containing residues of enrofloxacin to calves should be avoided up to the end of the milk withdrawal period (except during the colostral phase), because it could select antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria.

For repeated injection or for injection volumes exceeding 15 ml (cattle) or 7.5 ml (pigs, calves) in divided doses, a new site must be chosen for each injection.

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.

Use of the veterinary medicinal product deviating from the instructions given in this 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 is eliminated renally. As with all fluoroquinolones, delayed excretion can therefore be expected in the presence of existing renal damage.

Not for use for prophylaxis.

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

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician. If pain persists for more than 12 hours after medical examination, seek medical advice again.

People with known hypersensitivity to (fluoro)quinolones should avoid contact with the veterinary medicinal product.

Wash any splashes from skin or eyes immediately with water.

Do not eat, drink or smoke while handling the veterinary medicinal product.

#### Special precautions for the protection of the environment:

Not applicable.

### **3.6 Adverse events**

Cattle and pigs:

Very rare ( $<1$ animal / 10 000 animals treated, including isolated reports):	Injection site reddening <sup>1</sup> , Injection site swelling <sup>1</sup> Circulatory shock <sup>2</sup> Digestive tract disorders <sup>3</sup>
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<sup>1</sup> Transitory, regress within a few days without further therapeutic measures.

<sup>2</sup> With intravenous treatment in cattle.

<sup>3</sup> In calves.

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:

Can be used during pregnancy and lactation.

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

Combination of enrofloxacin with macrolides antibiotics or tetracyclines may produce antagonistic effects. The elimination of theophylline may be delayed.

### 3.9 Administration routes and dosage

Cattle:

Subcutaneous use (respiratory disease) or intravenous use (*E. coli* mastitis).

The dosage for respiratory disease is 7.5 mg enrofloxacin per kg body weight (BW) for a single treatment by subcutaneous (**s.c.**) administration.

This is equivalent to:

<b>7.5 ml of veterinary medicinal product per 100 kg BW per day</b>
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Do not administer more than 15 ml (cattle) or 7.5 ml (calf) per injection site (**s.c.**). In case of serious or chronic respiratory disease a second injection may be required after 48 hours.

The dosage for the treatment of *E. coli* mastitis is 5 mg enrofloxacin per kg (BW) by intravenous administration (**i.v.**).

This is equivalent to:

<b>5 ml of veterinary medicinal product per 100 kg BW per day</b>
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The treatment of *E. coli* mastitis should be exclusively by **i.v.** application on 2 to 3 consecutive days.

Pigs:

Intramuscular use.

The dosage for respiratory disease is 7.5 mg enrofloxacin per kg (BW) for a single treatment by intramuscular (**i.m.**) administration into the neck muscles behind the ear.

This is equivalent to:

<b>0.75 ml of veterinary medicinal product per 10 kg BW per day</b>
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Do not administer more than 7.5 ml per injection site (**i.m.**). In cases of serious or chronic respiratory disease a second injection may be required after 48 hours.

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

The stopper may be safely punctured up to 20 times.

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

In cattle a dose of 25 mg/kg bodyweight administered by the subcutaneous route for 15 consecutive days is tolerated without any clinical symptoms. Higher doses in cattle and doses of around 25 mg/kg and above in pigs may cause lethargy, lameness, ataxia, slight salivation and muscle tremors.

### **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:

Meat and offal:

**s.c.:** 14 days

**i.v.:** 7 days

Milk:

**s.c.:** 5 days

**i.v.:** 3 days

Pigs:

Meat and offal:

**i.m.:** 12 days

## **4. PHARMACOLOGICAL INFORMATION**

### **4.1 ATCvet code : QJ01MA90**

### **4.2 Pharmacodynamics**

#### Mode of action

Enrofloxacin belongs to the fluoroquinolone group of antibiotics. 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 Gram-positive and many Gram-negative bacteria such as *Histophilus somni*, *Mannheimia haemolytica*, *Pasteurella multocida*, *Mycoplasma* spp. and *E. coli* in cattle as well

as *Actinobacillus pleuropneumoniae*, *Pasteurella multocida* and *Haemophilus parasuis* in pigs 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.

Clinical breakpoints established by CLSI<sup>1</sup> in 2024 for enrofloxacin in cattle for bovine respiratory disease are as follows:

Organism	Minimum inhibitory concentration breakpoints of enrofloxacin (µg/ml)		
	susceptible	intermediate	resistant
<i>Histophilus somni</i>	≤0.25	0.5-1	≥2
<i>Mannheimia haemolytica</i>	≤0.25	0.5-1	≥2
<i>Pasteurella multocida</i>	≤0.25	0.5-1	≥2

Clinical breakpoints established by CLSI<sup>1</sup> in 2024 for enrofloxacin in pigs for porcine respiratory disease are as follows:

Organism	Minimum inhibitory concentration breakpoints of enrofloxacin (µg/ml)		
	susceptible	intermediate	resistant
<i>Actinobacillus pleuropneumoniae</i>	≤0.25	0.5	≥1
<i>Pasteurella multocida</i>	≤0.25	0.5	≥1

<sup>1</sup> CLSI. Performance standards for antimicrobial disk and dilution susceptibility tests for bacteria isolated from animals: 7th ed. CLSI supplement Vet01S Clinical and Laboratory Standards Institute

### **4.3 Pharmacokinetics**

Following subcutaneous administration of the veterinary medicinal product in cattle or intramuscular administration in pigs, the active substance, enrofloxacin, is absorbed very rapidly and almost completely (high bioavailability).

#### Cattle:

After subcutaneous administration at a dose rate of 7.5 mg enrofloxacin per kg body weight to non-lactating cattle peak plasma concentrations of 0.82 mg/L are reached within 5 hours. The overall drug exposure in plasma is 9.1 mg\*hr/L. Enrofloxacin is eliminated from the body at a half-life of 6.4 hr. Approximately 50% of enrofloxacin is metabolised to the active substance ciprofloxacin. Ciprofloxacin is eliminated from the body at a half-life of 6.8 hr.

After intravenous injection at a dose rate of 5.0 mg enrofloxacin per kg body weight to lactating cows, peak plasma concentrations of approx. 23 mg/L are reached immediately. The overall drug exposure in plasma is 4.4 mg\*hr/L. Enrofloxacin is eliminated from the body at a half-life of 0.9 hr. Approximately 50% of parent compound are metabolised to ciprofloxacin with peak plasma concentrations of 1.2 mg/L reached at 0.2 hr. Mean elimination half-life of ciprofloxacin is 2.1 hr. In milk the metabolite ciprofloxacin mainly accounts for antibacterial activity (approx. 90%). Ciprofloxacin reaches peak milk concentrations of 4 mg/L within 2 hr after intravenous dosing. Total

exposure in milk over 24 hours is approx. 21 mg\*hr/L. Ciprofloxacin is eliminated from milk at a half-life of 2.4 hr. Peak concentrations of 1.2 mg enrofloxacin per litre are reached in milk within 0.5 hours with a total enrofloxacin exposure in milk of approx. 2.2 mg\*hr/L. Enrofloxacin is eliminated from milk at 0.9 hr.

Pigs:

After intramuscular administration of 7.5 mg/kg body weight to pigs a mean peak serum concentration of 1.46 mg/L was achieved within 4 hours. The overall drug exposure over 24 hours was 20.9 mg\*hr/L. The drug was eliminated from the central compartment at a terminal half-life of 13.1 hr. With peak concentrations less than 0.06 mg/L mean serum concentrations of ciprofloxacin were very low.

Enrofloxacin has a high volume of distribution. The concentrations in the tissues and organs mostly significantly exceed serum levels. Organs in which high concentrations can be expected include the lungs, liver, kidneys, gut and muscle tissue.

Enrofloxacin is eliminated renally.

## **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**

Do not refrigerate or freeze.

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

Cardboard box with 1 brown glass bottle (glass type I, Ph. Eur.) of 100 ml with a chlorobutyl stopper secured by an aluminium crimp cap.

### **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**

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

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

Date of first authorisation: DD/MM/YYYY

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

DD month YYYY

**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**

**CARDBOARD BOX**

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

Baytril One 100 mg/ml solution for injection (AT, CY, CZ, EL, PT, PL, SK)

Baytril uno 100 mg/ml solution for injection (ES)

Baytril Max 100 mg/ml solution for injection (BG, HR, SI)

**2. STATEMENT OF ACTIVE SUBSTANCES**

Enrofloxacin 100 mg/ml

**3. PACKAGE SIZE**

100 ml

**4. TARGET SPECIES**

Cattle, pigs.

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Cattle: **s.c.** or **i.v.**

Pigs: **i.m.**

**7. WITHDRAWAL PERIODS**

Withdrawal periods:

Cattle:

Meat and offal:

**s.c.:** 14 days

**i.v.:** 7 days

Milk:

**s.c.:** 5 days

**i.v.:** 3 days

Pigs:

Meat and offal: **i.m.:** 12 days

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached use within 28 days.

<b>9. SPECIAL STORAGE PRECAUTIONS</b>
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Do not refrigerate or freeze.

<b>10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”</b>
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Read the package leaflet before use.

<b>11. THE WORDS “FOR ANIMAL TREATMENT ONLY”</b>
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For animal treatment only.

<b>12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”</b>
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Keep out of the sight and reach of children.

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

<b>14. MARKETING AUTHORISATION NUMBERS</b>
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<b>15. BATCH NUMBER</b>
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Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**LABEL**

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

Baytril One 100 mg/ml solution for injection (AT, CY, CZ, EL, PT, PL, SK)

Baytril uno 100 mg/ml solution for injection (ES)

Baytril Max 100 mg/ml solution for injection (BG, HR, SI)

**2. STATEMENT OF ACTIVE SUBSTANCES**

Enrofloxacin 100 mg/ml

**3. TARGET SPECIES**

Cattle, pigs.

**4. ROUTES OF ADMINISTRATION**

Cattle: **s.c.** or **i.v.**

Pigs: **i.m.**

**5. WITHDRAWAL PERIODS**

Withdrawal periods:

Cattle:

Meat and offal:

**s.c.:** 14 days

**i.v.:** 7 days

Milk:

**s.c.:** 5 days

**i.v.:** 3 days

Pigs:

Meat and offal: **i.m.:** 12 days

**6. EXPIRY DATE**

Exp. {mm/yyyy}


Once broached use within 28 days.

Once broached use by: \_\_\_\_\_

**7. SPECIAL STORAGE PRECAUTIONS**

Do not refrigerate or freeze.

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

<b>9. BATCH NUMBER</b>
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Lot {number}

## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Baytril One 100 mg/ml solution for injection for cattle and pig (AT, CY, CZ, EL, PT, PL, SK)

Baytril uno 100 mg/ml solution for injection for cattle and pig (ES)

Baytril Max 100 mg/ml solution for injection for cattle and pig (BG, HR, SI)

### 2. Composition

Each ml contains:

#### Active substance:

Enrofloxacin 100 mg

#### Excipients:

n- Butanol 30 mg

Benzyl alcohol (E1519) 20 mg

Clear, yellow solution.

### 3. Target species

Cattle, Pigs.

### 4. Indications for use

#### Cattle:

For the treatment of respiratory tract infections caused by *Histophilus somni*, *Mannheimia haemolytica*, *Pasteurella multocida* and *Mycoplasma* spp.

For the treatment of mastitis caused by *E. coli*.

#### Pigs:

For the treatment of bacterial bronchopneumonia caused by *Actinobacillus pleuropneumoniae*, *Haemophilus parasuis* and *Pasteurella multocida*.

### 5. Contraindications

Do not use in cases of hypersensitivity to the active substance, other (fluoro)quinolones or to any of the excipients.

Do not use in animals with central nervous system-associated seizure disorders, existing impairment of cartilage growth or damage to the locomotor apparatus involving joints subjected to heavy functional stresses or load-bearing joints.

### 6. Special warnings

#### Special warnings:

Cross-resistance has been shown between enrofloxacin and other (fluoro)quinolones in target pathogens, e.g. *Escherichia coli*. Use of the veterinary medicinal product should be carefully



considered when susceptibility testing has shown resistance to fluoroquinolones because its effectiveness may be reduced.

Special precautions for safe use in the target species:

For repeated injection or for injection volumes exceeding 15 ml (cattle) or 7.5 ml (pigs, calves) in divided doses, a new site must be chosen for each injection.

Enrofloxacin is eliminated renally. As with all fluoroquinolones, delayed excretion can therefore be expected in the presence of existing renal damage.

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach. Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

The veterinary medicinal product should only be used in individual animals

The feeding of waste milk containing residues of enrofloxacin to calves should be avoided up to the end of the milk withdrawal period (except during the colostral phase), because it could select antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria.

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.

Use of the veterinary medicinal product deviating from the instructions given in this package leaflet 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.

Not for use for prophylaxis.

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

In case of accidental self-injection seek medical advice immediately and show the package leaflet or label to the physician.

If pain persists for more than 12 hours after medical examination, seek medical advice again.

People with known hypersensitivity to (fluoro)quinolones should avoid contact with the veterinary medicinal product.

Wash any splashes from skin or eyes immediately with water.

Do not eat, drink or smoke while handling the veterinary medicinal product.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

Combination of enrofloxacin with macrolides antibiotics or tetracyclines may produce antagonistic effects. The elimination of theophylline may be delayed.

Overdose:

In cattle a dose of 25 mg/kg bodyweight administered by the subcutaneous route for 15 consecutive days is tolerated without any clinical symptoms. Higher doses in cattle and doses of around 25 mg/kg and above in pigs may cause lethargy, lameness, ataxia, slight salivation and muscle tremors.

#### 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 and pigs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Injection site reddening <sup>1</sup> , Injection site swelling <sup>1</sup> Circulatory shock <sup>2</sup> (Circulation failure) Digestive tract disorders <sup>3</sup>
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<sup>1</sup> Transitory, regress within a few days without further therapeutic measures.

<sup>2</sup> With intravenous treatment in cattle.

<sup>3</sup> In calves.

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 its local representative > 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**

#### Cattle:

Subcutaneous (**s.c.**) use (respiratory disease) or intravenous (**i.v.**) use (*E. coli* mastitis) .

The dosage for respiratory disease is 7.5 mg enrofloxacin per kg body weight (BW) for a single treatment by subcutaneous (**s.c.**) administration.

This is equivalent to:

<b>7.5 ml of veterinary medicinal product per 100 kg BW per day</b>
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Do not administer more than 15 ml (cattle) or 7.5 ml (calf) per injection site (**s.c.**). In case of serious or chronic respiratory disease a second injection may be required after 48 hours.

The dosage for the treatment of *E. coli* mastitis is 5 mg enrofloxacin per kg (BW) by intravenous administration (**i.v.**).

This is equivalent to:

<b>5 ml of veterinary medicinal product per 100 kg BW per day</b>
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The treatment of *E. coli* mastitis should be exclusively by **i.v.** application on 2 to 3 consecutive days.

#### Pigs:

Intramuscular (**i.m.**) use.

The dosage for respiratory disease is 7.5 mg enrofloxacin per kg (BW) for a single treatment by intramuscular (**i.m.**) administration into the neck muscles behind the ear.

This is equivalent to:

<b>0.75 ml of veterinary medicinal product per 10 kg BW per day</b>
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Do not administer more than 7.5 ml per injection site (**i.m.**). In cases of serious or chronic respiratory disease a second injection may be required after 48 hours.

The stopper may be safely punctured up to 20 times.

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

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

#### **10. Withdrawal periods**

##### Cattle:

Meat and offal:

**s.c.:** 14 days

**i.v.:** 7 days

Milk:

**s.c.:** 5 days

**i.v.:** 3 days

##### Pigs:

Meat and offal:

**i.m.:** 12 days

#### **11. Special storage precautions**

Keep out of the sight and reach of children.

Do not refrigerate or freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton 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**

Package size: 100 ml

**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 events>:

Manufacturer responsible for batch release:

KVP Pharma + Veterinär Produkte GmbH  
Projensdorfer Str. 324, D-24106 Kiel, Germany

<Local representatives <and contact details to report suspected adverse events>:>

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>

**17. Other information**

Enrofloxacin belongs to the fluoroquinolone group of antibiotics. The mode of action of enrofloxacin is bactericidal and bactericidal activity is concentration dependent.

Enrofloxacin is active against Gram-positive and many Gram-negative bacteria such as *Histophilus somni*, *Mannheimia haemolytica*, *Pasteurella multocida*, *Mycoplasma* spp. and *E. coli* in cattle as well as *Actinobacillus pleuropneumoniae*, *Pasteurella multocida* and *Haemophilus parasuis* in pigs at the recommended therapeutic doses.