

## **ANNEX I**

### **SUMMARY OF PRODUCT CHARACTERISTICS**

(Based on the current SPC of the reference product  
Baytril RSI 100 mg/ml Injektionslösung für Rinder und Schweine)

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril Direct 100 mg/ml Injektionslösung für Schweine [AT]  
Baytril Inject 100 mg/ml solution for injection for pigs [BE, LU, NL]  
Baytril Inject – Soluzione iniettabile 100mg/ml per suini [IT]  
Baytril Max 100 mg/ml solution for injection for pigs [IE, UK]

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

### Active substance:

Enrofloxacin 100 mg

### Excipient(s):

n-Butanol 30 mg

Benzyl alcohol (E 1519) 20 mg

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Solution for  
injection Clear,  
yellow solution

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Pig

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

For the treatment of bacterial bronchopneumonia caused by enrofloxacin-sensitive *Actinobacillus pleuropneumoniae*, *Pasteurella multocida* and complicated by *Haemophilus parasuis* as secondary pathogen in pigs.

### 4.3 Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients. Do not use in case of resistance against other fluoroquinolone due to the potential for cross-resistance. Do not use in animals with central nervous system-associated seizure disorders. Do not use in the presence of existing disorders of cartilage development or musculoskeletal damage around functionally significant or weight-bearing joints. Do not use for prophylaxis.

### 4.4 Special warnings for each target species

None.

## **4.5 Special precautions for use**

### Special precautions for use in animals

Repeated injections should be administered at different sites.

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

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

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

Direct contact with the skin should be avoided due to sensitisation, contact dermatitis and possible hypersensitivity reactions.

Wash any splashes from skin or eyes immediately with water. Do not eat, drink or smoke while handling the product.

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

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

In rare cases, transitory inflammatory reactions (swelling, redness) can occur at the injection site. These regress within a few days without further therapeutic measures.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports)

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

May be used during pregnancy and lactation.

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

Antagonist effects due to concurrent administration of bacteriostatic antimicrobial agents such as macrolides or tetracyclines and phenicols 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

The dosage for respiratory tract infections is 7.5 mg enrofloxacin per kg body weight for a single administration.

This corresponds to

**0.75 ml Baytril Inject solution for injection per 10 kg body weight per day**

No more than 7.5 ml should be administered at any one injection site. In cases of severe or chronic respiratory tract infections, a second injection may be required after 48 hours.

#### Method of administration:

The intramuscular injection should be made into the neck at the ear base. Repeated injections should be made at different injection sites.

To ensure administration of the correct dosage, body weight should be determined as accurately as possible to avoid underdosing. The stopper may be safely punctured up to 20 times.

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

Doses of around 25 mg active ingredient per kg body weight and above may cause lethargy, loss of appetite and ataxia. No information is available on the tolerability of doses several times higher than the therapeutic dose (over the recommended or a prolonged treatment period). Do not exceed the recommended dose. In accidental overdose there is no antidote and treatment should be symptomatic.

#### 4.11 Withdrawal period(s)

Meat and offal: 12 days

### 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antibacterials for systemic use,  
Fluoroquinolones, ATCvet code: QJ01MA90

#### 5.1 Pharmacodynamic properties

Enrofloxacin has a spectrum of activity which includes *Actinobacillus pleuropneumoniae*, *Pasteurella multocida* and *Haemophilus parasuis*.

Enrofloxacin belongs to the fluoroquinolone group of antibiotics. The substance has bactericidal activity which is mediated by binding to subunit A of DNA gyrase and the resulting selective inhibition of this enzyme.

DNA gyrase is a topoisomerase. These enzymes are involved in the replication, transcription and recombination of bacterial DNA. Fluoroquinolones also influence bacteria in the stationary phase by altering cell wall permeability.

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.

The inhibitory and bactericidal concentrations of enrofloxacin are very close, being either identical or differing by no more than 1-2 dilution steps.

## **5.2 Pharmacokinetic particulars**

Following intramuscular administration in pigs, the active ingredient enrofloxacin is absorbed very rapidly and almost completely (high bioavailability). Peak serum concentrations of the active ingredient are reached after 1- 2 hours.

Therapeutic concentrations are maintained for a period of at least 48 hours.

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.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Arginin  
e n-  
Butanol  
Benzyl alcohol (E  
1519) Water for  
injection

### **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 in the unopened container: 3  
years Shelf life after first opening of the container: 28 days

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

Protect from frost.

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

Carton box containing one 100 ml brown glass (Type 1) bottle with chlorobutyl rubber stopper secured by an aluminium crimp cap.

### **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials 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**

{Name and address}

<{tel}>  
<{fax}>  
<{e-mail}>

**8.     MARKETING AUTHORISATION NUMBER(S)**

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

Date of first authorisation: {DD/MM/YYYY}

Date of last renewal: {DD/MM/YYYY}...

**10    DATE OF REVISION OF THE TEXT**

{MM/YYYY}

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

Prescription- and pharmacy-only medicine, repeat dispensing prohibited.

### **ANNEX III**

#### **LABELLING AND PACKAGE LEAFLET**

(Based on the current SPC of the reference product  
Baytril RSI 100 mg/ml Injektionslösung für Rinder und Schweine)

## **A. LABELLING**



**PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE**

**Card box and bottle label**

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

Baytril Direct 100 mg/ml Injektionslösung für Schweine [AT]  
Baytril Inject 100 mg/ml solution for injection for pigs [BE, LU, NL]  
Baytril Inject – Soluzione iniettabile 100mg/ml per suini [IT]  
Baytril Max 100 mg/ml solution for injection for pigs [IE, UK]

Enrofloxacin

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

1 ml contains:

**Active substance:**

Enrofloxacin 100  
mg

**Excipients:**

n-Butanol 30 mg  
Benzyl alcohol (E 1519) 20 mg

**3. PHARMACEUTICAL FORM**

Solution for injection

**4. PACKAGE SIZE**

100 ml

**5. TARGET SPECIES**

Pig

**6. INDICATION(S)**

For the treatment of bacterial bronchopneumonia caused by enrofloxacin-sensitive *Actinobacillus pleuropneumoniae*, *Pasteurella multocida* and complicated by *Haemophilus parasuis* as secondary pathogen in pigs.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For intramuscular injection. Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

Meat and offal: 12 days

**9. SPECIAL WARNING(S), IF NECESSARY**

Accidental injection is dangerous. Read package leaflet before use.

**10. EXPIRY DATE**

EXP: month/ year

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

Once broached use by .../.....

**11. SPECIAL STORAGE CONDITIONS**

Protect from frost.

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Dispose of waste material in accordance with local requirements.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable**

For animal treatment only. To be supplied only on veterinary prescription.

**14. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

{Name and address}

<{tel}>

<{fax}>

<{e-mail}>

**16. MARKETING AUTHORISATION NUMBER(S)**

**17. MANUFACTURER’S BATCH NUMBER**

Lot {number}

## **B. PACKAGE LEAFLET**

**PACKAGE LEAFLET**  
**Baytril® 1inject - 100 mg/ml solution for injection for pig**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder:

National Bayer Animal Health subsidiary

Manufacturer for batch release:

KVP Pharma + Veterinär Produkte GmbH

Projensdorfer Str. 324

D-24106 Kiel

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

Baytril Direct 100 mg/ml Injektionslösung für Schweine [AT]

Baytril 1inject 100 mg/ml solution for injection for pigs [BE, LU, NL]

Baytril Inject – Soluzione iniettabile 100mg/ml per suini [IT]

Baytril Max 100 mg/ml solution for injection for pigs [IE, UK]

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**

1 ml contains:

**Active substance:**

Enrofloxacin                      100 mg

**Excipients:**

n-Butanol                              30 mg

Benzyl alcohol (E 1519)              20 mg

clear yellow solution

**4. INDICATION(S)**

For the treatment of bacterial bronchopneumonia caused by enrofloxacin-sensitive *Actinobacillus pleuropneumoniae*, *Pasteurella multocida* and complicated by *Haemophilus parasuis* as secondary pathogen in pigs.

**5. CONTRAINDICATIONS**

Do not use in case of hypersensitivity to the active substance or to any of the excipients. Do not use in case of resistance against other fluoroquinolone due to the potential for cross-resistance.

Do not use in animals with central nervous system-associated seizure disorders. Do not use in the presence of existing disorders of cartilage development or musculoskeletal damage around functionally significant or weight-bearing joints. Do not use for prophylaxis.

## 6. ADVERSE REACTIONS

In rare cases, transitory inflammatory reactions (swelling, redness) can occur at the injection site. These regress within a few days without further therapeutic measures.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals )
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Pig

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The dosage for respiratory tract infections is 7.5 mg enrofloxacin per kg body weight for a single administration. This corresponds to

0.75 ml Baytril Inject solution for injection per 10 kg body weight per day
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No more than 7.5 ml should be administered at any one injection site.

In cases of severe or chronic respiratory tract infections, a second injection may be required after 48 hours.

### Method of administration:

The intramuscular injection should be made into the neck at the ear base. Repeated injections should be made at different injection sites.

The stopper may be safely punctured up to 20 times.

## 9. ADVICE ON CORRECT ADMINISTRATION

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

## 10. WITHDRAWAL PERIOD

Meat and offal: 12 days

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.  
Protect from frost.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and label 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 WARNING(S)

### Special precautions for use in animals

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

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

People with known hypersensitivity to (fluoro)quinolones should avoid contact with the veterinary medicinal product.  
Direct contact with the skin should be avoided due to sensitisation, contact dermatitis and possible hypersensitivity reactions.  
Wash any splashes from skin or eyes immediately with water. Do not eat, drink or smoke while handling the product.  
Avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.

### Pregnancy:

May be used during pregnancy

### Lactation:

May be used during lactation.

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

Antagonist 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

### Overdose (symptoms, emergency procedures, antidotes):

Doses of around 25 mg active ingredient per kg body weight and above may cause lethargy, loss of appetite and ataxia. No information is available on the tolerability of doses several times higher than the therapeutic dose (over the recommended or a prolonged treatment period).  
Do not exceed the recommended dose. In accidental overdose there is no antidote and treatment should be symptomatic.

Incompatibilities:

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

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

**15. OTHER INFORMATION**

Package sizes: 100 ml

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