1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril 100 mg/ml solution for use in drinking water for chickens, turkeys and rabbits

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
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**
Benzyl alcohol (E1519)	14 mg
Potassium hydroxide	
Purified water	

Clear yellowish solution.

3. CLINICAL INFORMATION

3.1 Target species

Chickens, turkeys and rabbits.

3.2 Indications for use for each target species

For the treatment of the respiratory tract and of the digestive tract infections caused by the following bacteria:

Chickens:
Avibacterium paragallinarum, Pasteurella multocida, Mycoplasma gallisepticum, Mycoplasma synoviae.

Turkeys:
Pasteurella multocida, Mycoplasma gallisepticum, Mycoplasma synoviae.

Rabbits:
Pasteurella multocida and bacterial enteritis due to infection with *E. coli.*

3.3 Contraindications

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

3.4 Special warnings

Treatment of *Mycoplasma* spp. infections may not eradicate the organism.
Resistance has been reported in *Mycoplasma synoviae* in the EU.
Cross-resistance has been shown between enrofloxacin and other fluoroquinolones 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:

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 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.

Not for use for prophylaxis.

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.

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

People with known hypersensitivity to fluoroquinolones should avoid contact with the veterinary medicinal product..
Avoid contact with skin and eyes.
In case of accidental spillage onto skin or eyes, rinse immediately with water, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands and exposed skin after use.
Do not eat, drink or smoke whilst using the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

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

Laying birds:
Do not use in laying hens producing eggs for human consumption.
Do not administer to layer replacement birds within 14 days before the start of the laying period.

3.8 Interaction with other medicinal products and other forms of interaction

In vitro, an antagonism was shown, when combining fluoroquinolones with bacteriostatic antimicrobial agents such as macrolides or tetracyclines and phenicols. The simultaneous application of substances containing aluminium or magnesium can impair the absorption of enrofloxacin.

3.9 Administration routes and dosage

In drinking water use.

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

Always make sure that the entire dose offered has been consumed. The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of enrofloxacin may need to be adjusted accordingly. The medicated water should be made up fresh each day just before it is offered to the animals. The drinking water must be medicated throughout the treatment period, and no other water source should be available.

Use only fresh pre-solutions, prepared every day before start of treatment. Pumping systems should be checked constantly to assure proper medication. Empty the water system and fill it with medicated water before starting the treatment.

The veterinary medicinal product may be put directly into the header tank or introduced via a water proportioner pump.

Chickens and turkeys:
10 mg enrofloxacin/kg bodyweight per day for 3–5 consecutive days.

Treatment for 3–5 consecutive days; for 5 consecutive days in mixed infections and chronic progressive forms.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily quantity of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{0.1 \text{ ml of veterinary medicinal product} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily water intake (l/animal)}} = \text{ml veterinary medicinal product per litre of drinking water}$$

Rabbits:
10 mg/kg bodyweight per day for 5 consecutive days.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily quantity of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{0.1 \text{ ml of veterinary medicinal product} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily water intake (l/animal)}} = \text{ml veterinary medicinal product per litre of drinking water}$$

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

No adverse clinical symptoms were observed in chickens and turkeys treated respectively with doses up to 10 and 6 times higher than the therapy dose.
The use of fluoroquinolones during the growth phase combined with a marked and prolonged increase in the intake of drinking water, and hence active ingredient, possibly due to high temperatures, may potentially be associated with damage of the articular cartilage.

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

Chickens: Meat and offal: 7 days.
Turkeys: Meat and offal: 13 days.
Not for use in birds producing eggs for human consumption.
Do not administer to layer replacement birds within 14 days before the start of the laying period.

Rabbits: Meat and offal: 3 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. They modulate the topological state of DNA through cleaving and resealing reactions. Initially, both strands of the DNA double helix are cleaved. Then, a distant segment of DNA is passed through this break before the strands are resealed. Target inhibition is caused by non-covalent binding of fluoroquinolone molecules to an intermediate state in this sequence of reactions, in which DNA is cleaved, but both strands are retained covalently attached to the 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.

Antibacterial spectrum:
Enrofloxacin is active against many Gram-negative bacteria, against Gram-positive bacteria and *Mycoplasma* spp.
In vitro susceptibility has been shown in strains of (i) Gram-negative species such as *Avibacterium (Haemophilus) paragallinarum* and *Pasteurella multocida* and (ii) *Mycoplasma gallisepticum* and *Mycoplasma synoviae*. (See section 3.5).

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.

Resistance of *Mycoplasma gallisepticum* and *Mycoplasma synoviae* to enrofloxacin has been reported in chickens and turkeys.

4.3 Pharmacokinetics

Enrofloxacin administered via drinking water to poultry is rapidly and very well absorbed with a bioavailability of approx. 90 %. Maximum plasma concentrations of 2 mg/l are reached within 1.5 hours after a single bolus dose rate of 10 mg/kg body weight with a total systemic availability of 14.4 mg·hr/l. Enrofloxacin is eliminated from the body with a total body clearance of 10.3 ml/min·kg. If dosed as continuous drinking water medication (multiple dosing) steady-state concentrations of 0.5 mg (turkeys) to 0.8 mg (chicken) enrofloxacin per litre are achieved. A high mean volume of distribution (5 l/kg) indicates good tissue penetration of enrofloxacin. Concentrations in target tissues like lungs, liver, kidney, intestine and muscle tissue, exceed plasma concentrations by far. In poultry enrofloxacin is poorly metabolized to its active metabolite ciprofloxacin (approximately 5 %).

Enrofloxacin is eliminated from the body at a half-life of 6 hours. Protein binding in poultry is approximately 25 %.

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.

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing biocidal products, feed additives or other substances used in drinking water.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.
Shelf life after first opening the immediate packaging: 12 weeks.
Shelf life after dilution according to directions: 24 hours.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

100 ml, 500 ml and 1,000 ml high density polyethylene (HDPE) bottles with an HDPE insert and a polypropylene screw closure.
5,000 ml HDPE canister with an aluminium/HDPE seal and an HDPE screw closure.
The containers are provided with a graduated polypropylene measuring cup.

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

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

DD/MM/YYYY

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

MM/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*).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX: 100 ML, 500 ML

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril 100 mg/ml solution for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Enrofloxacin 100 mg/ml

3. PACKAGE SIZE

100 ml
500 ml

4. TARGET SPECIES

Chickens, turkeys and rabbits.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Chickens: Meat and offal: 7 days.
Turkeys: Meat and offal: 13 days.
Not for use in birds producing eggs for human consumption. Do not administer to layer replacement birds within 14 days before the start of the laying period.

Rabbits: Meat and offal: 3 days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 12 weeks.
Once opened use by _____
Once diluted use within 24 hours.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco logo

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

FOLD-OUT LABEL (Without outer carton): 500 ml, 1,000 ml, 5,000 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril 100 mg/ml solution for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Enrofloxacin 100 mg/ml

3. PACKAGE SIZE

500 ml
1,000 ml
5,000 ml

4. TARGET SPECIES

Chickens, turkeys and rabbits.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Chickens: Meat and offal: 7 days.
Turkeys: Meat and offal: 13 days.
Not for use in birds producing eggs for human consumption. Do not administer to layer replacement birds within 14 days before the start of the laying period.

Rabbits: Meat and offal: 3 days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 12 weeks.
Once opened use by _____
Once diluted use within 24 hours.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco logo

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

BOTTLE LABEL: 100 ML, 500 ML

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril 100 mg/ml solution for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Enrofloxacin 100 mg/ml

100 ml
500 ml

3. TARGET SPECIES

Chickens, turkeys and rabbits.

4. ROUTES OF ADMINISTRATION

In drinking water use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Chickens: Meat and offal: 7 days.
Turkeys: Meat and offal: 13 days.
Not for use in birds producing eggs for human consumption. Do not administer to layer replacement birds within 14 days before the start of the laying period.

Rabbits: Meat and offal: 3 days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 12 weeks.
Once opened use by _____
Once diluted use within 24 hours.

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco logo

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Baytril 100 mg/ml solution for use in drinking water for chickens, turkeys and rabbits

2. Composition

Each ml contains:

Active substances:
Enrofloxacin 100 mg

Excipients:
Benzyl alcohol 14 mg.

Clear yellowish solution.

3. Target species

Chickens, turkeys and rabbits.

4. Indications for use

For the treatment of the respiratory tract and of the digestive tract infections caused by the following bacteria:

Chickens:
Avibacterium paragallinarum, Pasteurella multocida, Mycoplasma gallisepticum, Mycoplasma synoviae.

Turkeys:
Pasteurella multocida, Mycoplasma gallisepticum, Mycoplasma synoviae.

Rabbits:
Pasteurella multocida and bacterial enteritis due to infection with *E. coli.*

5. Contraindications

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

6. Special warnings

Special warnings:
Treatment of *Mycoplasma* spp. infections may not eradicate the organism.
Resistance has been reported in *Mycoplasma synoviae* in the EU.
Cross-resistance has been shown between enrofloxacin and other fluoroquinolones 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:
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 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.

Not for use for prophylaxis.

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to fluoroquinolones should avoid contact with the veterinary medicinal product.
Avoid contact with skin and eyes.
In case of accidental spillage onto skin or eyes, rinse immediately with water, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands and exposed skin after use.
Do not eat, drink or smoke whilst using the veterinary medicinal product.

Laying birds:
Do not use in laying hens producing eggs for human consumption.
Do not administer to layer replacement birds within 14 days before the start of the laying period.

Interaction with other medicinal products and other forms of interaction:
In vitro, an antagonism was shown, when combining fluoroquinolones with bacteriostatic antimicrobial agents such as macrolides or tetracyclines and phenicols. The simultaneous application of substances containing aluminium or magnesium can impair the absorption of enrofloxacin.

Overdose:
No adverse clinical symptoms were observed in chickens and turkeys treated respectively with doses up to 10 and 6 times higher than the therapy dose.
The use of fluoroquinolones during the growth phase combined with a marked and prolonged increase in the intake of drinking water, and hence active ingredient, possibly due to high temperatures, may potentially be associated with damage of the articular cartilage.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.
No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing biocidal products, feed additives or other substances used in drinking water.

7. Adverse events

None known.

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

In drinking water use.

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

Chickens and turkeys:
10 mg enrofloxacin/kg bodyweight per day for 3–5 consecutive days.

Treatment for 3–5 consecutive days; for 5 consecutive days in mixed infections and chronic progressive forms.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily quantity of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{0.1 \text{ ml of veterinary medicinal product} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily water intake (l/animal)}} = \text{ml veterinary medicinal product per litre of drinking water}$$

Rabbits:
10 mg/kg bodyweight per day for 5 consecutive days.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily quantity of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{0.1 \text{ ml of veterinary medicinal product} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily water intake (l/animal)}} = \text{ml veterinary medicinal product per litre of drinking water}$$

9. Advice on correct administration

Always make sure that the entire dose offered has been consumed. The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of enrofloxacin may need to be adjusted accordingly. The medicated water should be made up fresh each day just before it is offered to the animals. The drinking water must be medicated throughout the treatment period, and no other water source should be available.

Use only fresh pre-solutions, prepared every day before start of treatment. Pumping systems should be checked constantly to assure proper medication. Empty the water system and fill it with medicated water before starting the treatment.

The veterinary medicinal product may be put directly into the header tank or introduced via a water proportioner pump.

10. Withdrawal periods

Chickens: Meat and offal: 7 days.
Turkeys: Meat and offal: 13 days.
Not for use in birds producing eggs for human consumption. Do not administer to layer replacement birds within 14 days before the start of the laying period.

Rabbits: Meat and offal: 3 days.

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.

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

Shelf-life after first opening the immediate packaging: 12 weeks.
Shelf life after dilution according to directions: 24 hours.
When an immediate packaging is opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the immediate packaging should be discarded should be worked out. This discard date should be written in the space provided.

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 national collection systems applicable to the veterinary medicinal product concerned. 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

Bottles of 100, 500 and 1,000 ml or canister of 5,000 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*).

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.>

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - <u>COMBINED LABEL AND PACKAGE LEAFLET</u>

BOTTLE OR CANISTER (1,000 ML AND 5,000 ML)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril 100 mg/ml solution for use in drinking water

2. COMPOSITION

Each ml contains:

Active substances:
Enrofloxacin 100 mg

Excipients:
Benzyl alcohol 14 mg.

Clear yellowish solution.

3. PACKAGE SIZE

1,000 ml
5,000 ml

4. TARGET SPECIES

Chickens, turkeys and rabbits.

5. INDICATIONS FOR USE

Indications for use
For the treatment of the respiratory tract and of the digestive tract infections caused by the following bacteria:

Chickens:
Avibacterium paragallinarum, Pasteurella multocida, Mycoplasma gallisepticum, Mycoplasma synoviae.

Turkeys:
Pasteurella multocida, Mycoplasma gallisepticum, Mycoplasma synoviae.

Rabbits:
Pasteurella multocida and bacterial enteritis due to infection with *E. coli.*

6. CONTRAINDICATIONS

Contraindications

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

7. SPECIAL WARNINGS

Special warnings

Special warnings:

Treatment of *Mycoplasma* spp. infections may not eradicate the organism.
Resistance has been reported in *Mycoplasma synoviae* in the EU.
Cross-resistance has been shown between enrofloxacin and other fluoroquinolones 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:

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 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.

Not for use for prophylaxis.

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.

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

People with known hypersensitivity to fluoroquinolones should avoid contact with the veterinary medicinal product.
Avoid contact with skin and eyes.
In case of accidental spillage onto skin or eyes, rinse immediately with water, seek medical advice immediately and show the label to the physician.
Wash hands and exposed skin after use.
Do not eat, drink or smoke whilst using the veterinary medicinal product.

Laying birds:

Do not use in laying hens producing eggs for human consumption.
Do not administer to layer replacement birds within 14 days before the start of the laying period.

Interaction with other medicinal products and other forms of interaction:

In vitro, an antagonism was shown, when combining fluoroquinolones with bacteriostatic antimicrobial agents such as macrolides or tetracyclines and phenicols. The simultaneous application of substances containing aluminium or magnesium can impair the absorption of enrofloxacin.

Overdose:

No adverse clinical symptoms were observed in chickens and turkeys treated respectively with doses up to 10 and 6 times higher than the therapy dose.

The use of fluoroquinolones during the growth phase combined with a marked and prolonged increase in the intake of drinking water, and hence active ingredient, possibly due to high temperatures, may potentially be associated with damage of the articular cartilage.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.
No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing biocidal products, feed additives or other substances used in drinking water.

8. ADVERSE EVENTS

Adverse events
None known.

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}

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration
In drinking water use.

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

Chickens and turkeys:
10 mg enrofloxacin/kg bodyweight per day for 3–5 consecutive days.

Treatment for 3–5 consecutive days; for 5 consecutive days in mixed infections and chronic progressive forms.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily quantity of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{0.1 ml of veterinary medicinal product} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily water intake (l/animal)}} = \text{ml veterinary medicinal product per litre of drinking water}$$

Rabbits:
10 mg/kg bodyweight per day for 5 consecutive days.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily quantity of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{0.1 ml of veterinary medicinal product} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily water intake (l/animal)}} = \text{ml veterinary medicinal product per litre of drinking water}$$

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration
Always make sure that the entire dose offered has been consumed. The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of enrofloxacin may need to be adjusted accordingly. The medicated water should be made up fresh each day just before it is offered to the animals. The drinking water must be medicated throughout the treatment period, and no other water source should be available.

Use only fresh pre-solutions, prepared every day before start of treatment. Pumping systems should be checked constantly to assure proper medication. Empty the water system and fill it with medicated water before starting the treatment.

The veterinary medicinal product may be put directly into the header tank or introduced via a water proportioner pump.

11. WITHDRAWAL PERIODS

Withdrawal periods
Chickens: Meat and offal: 7 days.
Turkeys: Meat and offal: 13 days.
Not for use in birds producing eggs for human consumption. Do not administer to layer replacement birds within 14 days before the start of the laying period.

Rabbits: Meat and offal: 3 days.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions
Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.
When an immediate packaging is opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the immediate packaging should be discarded should be worked out. This discard date should be written in the space provided.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

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 national collection systems applicable to the veterinary medicinal product concerned. These measures should help to protect the environment.

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

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products
Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack sizes
Bottles of 100, 500 and 1,000 ml or canister of 5,000 ml.

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label 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*).

17. CONTACT DETAILS

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.>

18. OTHER INFORMATION

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Once opened use within 12 weeks.

Once opened use by _____
Once diluted use within 24 hours.

21. BATCH NUMBER

Lot {number}