

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE Cardboard Box (100 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

**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.

Rabbits: Meat and offal: 3 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.

**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 GmbH

**14. MARKETING AUTHORISATION NUMBERS**

Vm 52127/5104

**15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE Bottle or Canister Label**

**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. 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.

Rabbits: Meat and offal: 3 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.

**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 GmbH

**9. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE 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 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 using the contact details at the end of this leaflet, or via your national reporting system at <https://www.gov.uk/report-veterinary-medicine-problem>.

**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.

Rabbits: Meat and offal: 3 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.

## **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.

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**

Vm 52127/5104

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

Not all pack sizes may be marketed.

## **15. PID LINK (Do not print heading)**

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

## **16. Contact details**

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

Elanco GmbH  
Heinz-Lohmann Strasse 4  
Grodan  
27472 Cuxhaven  
Germany

[PV.GBR@elancoah.com](mailto:PV.GBR@elancoah.com)

Tel: +44 3308221732

Manufacturer responsible for batch release:

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

**17. Other information**

POM-V

Veterinary medicinal product subject to prescription

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet 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 on this label, 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 using the contact details on this label, or via your national reporting system at <https://www.gov.uk/report-veterinary-medicine-problem>.

## 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:

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## 10. ADVICE ON CORRECT ADMINISTRATION

### Advice on correct administration

Always make sure that the entire dose offered has been consumed. 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.

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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.

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Rabbits: Meat and offal: 3 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.

## **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.

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.

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

### **Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## 15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 52127/5104

### Pack sizes

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

Not all pack sizes may be marketed.

## 16. PID LINK (Do not print heading)

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## 17. CONTACT DETAILS

### Contact details

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

Elanco GmbH  
Heinz-Lohmann-Str.4  
Groden  
27472 Cuxhaven  
Germany

[PV.GBR@elancoah.com](mailto:PV.GBR@elancoah.com)

Tel: +44 3308221732

Manufacturer responsible for batch release:

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

## 18. OTHER INFORMATION

### Other information

POM-V
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 Veterinary medicinal product subject to prescription

## 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}

*Gavin Hall*  
Approved: 13 February 2026