

PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril 25 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Enrofloxacin 25 mg/ml.

3. PACKAGE SIZE

50 ml,
100 ml.

4. TARGET SPECIES

Dogs, cats, pigs (piglets), rabbits, rodents, reptiles and ornamental birds

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

i.m., s.c.

Read the package leaflet before use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Pigs:

Meat and offal: 13 days.

Rabbits:

Meat and offal: 6 days.

Do not use in birds intended for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not refrigerate or freeze

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 52127/5119

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE LABEL GLASS
VIAL (100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril 25 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Enrofloxacin 25 mg/ml

3. TARGET SPECIES

Dogs, cats, pigs (piglets), rabbits, rodents, reptiles and ornamental birds

4. ROUTES OF ADMINISTRATION

i.m., s.c.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Pigs:

Meat and offal: 13 days.

Rabbits:

Meat and offal: 6 days.

Do not use in birds intended for human consumption.

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH 

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS VIAL (50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Enrofloxacin 25 mg/ml

50 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

Once broached use by ...

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Baytril 25 mg/ml solution for injection

2. Composition

Each ml contains: 25 mg enrofloxacin as active substance and 30 mg n-butyl alcohol as preservative.

Clear light-yellow solution

3. Target species

Dogs, cats, pigs (piglets), rabbits, rodents, reptiles and ornamental birds

4. Indications for use

Dogs

Treatment of infections of the alimentary, respiratory and urogenital tracts (including prostatitis, adjunctive antibiotic therapy for pyometra), skin and wound infections, otitis (externa/media) caused by strains of *Staphylococcus* spp., *Escherichia coli*, *Bordetella* spp., *Klebsiella* spp., *Pasteurella* spp., *Proteus* spp. and *Pseudomonas* spp.

Cats

Treatment of infections of the alimentary, respiratory and urogenital tracts (as adjunctive antibiotic therapy for pyometra), skin and wound infections, caused by strains of *Staphylococcus* spp., *Escherichia coli*, *Bordetella* spp., *Klebsiella* spp., *Pasteurella* spp., *Proteus* spp. and *Pseudomonas* spp.

Pigs (piglets)

Treatment of infections of the respiratory tract caused by strains of: *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Mycoplasma* spp.

Treatment of infections of the alimentary tract caused by strains of *Escherichia coli*.

Treatment of septicaemia caused by strains of *Escherichia coli*.

Rabbits

Treatment of infections of the alimentary and respiratory tracts caused by strains of: *Staphylococcus* spp., *Escherichia coli* and *Pasteurella multocida*.

Treatment of skin and wound infections caused by strains of *Staphylococcus aureus*.

Rodents, reptiles and ornamental birds

Treatment of infections of the alimentary and respiratory tracts where clinical experience, if possible, indicates enrofloxacin as the substance of choice.

5. Contraindications

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

Do not use in animals that are epileptic or suffer from seizures since enrofloxacin may cause CNS stimulation.

Do not use in young dogs during their growth, i.e. in small breeds of dogs less than 8 months of age, in big breeds of dogs less than 12 months of age, in giant breeds of dogs less than 18 months of age.

Do not use in cats less than 8 weeks of age.

6. Special warnings

Special warnings:

Cross-resistance has been shown between fluoroquinolones in *Escherichia coli* and other target pathogens. Use of the 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:

Use of the 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 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 product should only be used in individual animals

Special caution should be taken when using enrofloxacin in animals with impaired renal function.

Special caution should be taken when using enrofloxacin in cats because higher doses than recommended can cause retinal damage and blindness (see Overdose).

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

Enrofloxacin may cause hypersensitivity (allergic reactions). People with known hypersensitivity to fluoroquinolones (e.g., enrofloxacin or ciprofloxacin) should avoid any contact with the veterinary medicinal product.

The product may be irritating to skin and eyes. In case of contact with skin or eyes, wash the affected area with clear running water.

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

Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Other precautions:

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

Pregnancy and lactation:

Mammals:

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

Laying birds and reptiles:

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

Interaction with other medicinal products and other forms of interaction:

Do not use enrofloxacin concomitantly with antimicrobial substances acting antagonistically to quinolones (e.g. macrolides, tetracyclines or phenicols). Do not use concurrently with theophylline as the elimination of theophylline may be delayed.

Care should be taken during the concomitant use of flunixin and enrofloxacin in dogs to avoid adverse drug reactions. The decrease in drug clearances as a result of co-administration of flunixin and enrofloxacin indicates that these substances interact during the elimination phase. Thus, in dogs, the co-administration of enrofloxacin and flunixin increased the AUC and the elimination half-life of flunixin and increased the elimination half-life and reduced the C_{max} of enrofloxacin.

Overdose:

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

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

Cats have been shown to suffer ocular damage after receiving doses of more than 15 mg/kg once daily for 21 consecutive days. Doses of 30 mg/kg given once daily for 21 consecutive days have been shown to cause irreversible ocular damage. At 50 mg/kg given once daily for 21 consecutive days, blindness can occur.

In dogs, rabbits, small rodents, reptiles and birds, overdose has not been documented. In accidental overdose there is no antidote and treatment should be symptomatic.

Major incompatibilities:

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

7. Adverse events

Dogs, cats, pigs (piglets), rabbits, rodents, reptiles and ornamental birds.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site inflammation ¹ , Injection site reaction (e.g. oedema) ² , Injection site reddening ³ , Injection site ulcer ^{3,4} , Excitation Digestive tract disorders (e.g. diarrhoea, vomiting) ⁵ Anaphylaxis (severe allergic reaction) Ataxia (incoordination), Seizure, Tremor Bruising ⁶ Anorexia ⁵
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Commented [AS1]: Added following EU PVAR2 RtQ

¹ In pigs, after intramuscular administration. May persist up to 28 days after injection.

² In dogs. Moderate and transient.

³ In rabbits. May persist at least up to 17 days after injection.

⁴ With deep loss of tissue.

⁵ Mild and transient.

⁶ In reptiles and ornamental birds. Of muscles.

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:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

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

Subcutaneous (s.c) or intramuscular use (i.m).

To ensure a correct dosage, body weight (bw) should be determined as accurately as possible to avoid underdosing.

Dogs and cats:

5 mg of enrofloxacin/kg bw, corresponding to 1 ml/5 kg bw, daily by subcutaneous injection for up to 5 days.

Treatment may be initiated with injectable product and maintained with enrofloxacin tablets. Duration of treatment should be based on the duration of treatment approved for the appropriate indication in the product information of the tablet product.

Pigs (piglets):

2.5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily by intramuscular injection for 3 days.

Alimentary tract infection or septicaemia caused by *Escherichia coli*: 5 mg of enrofloxacin/kg of bw, corresponding to 2 ml/10 kg bw, once daily by intramuscular injection for 3 days.

In pigs, the injection should be made in the neck at the ear base.

Not more than 3 ml should be administered at one intramuscular injection site.

Rabbits:

10 mg/kg bw, corresponding to 2 ml/5 kg bw, once daily by subcutaneous injection for 5 to 10 consecutive days.

Rodents:

10 mg/kg bw, corresponding to 0.4 ml/kg bw, once daily by subcutaneous injection for 5 to 10 consecutive days. If necessary, depending on the severity of clinical signs, this dosage can be doubled.

Reptiles:

Reptiles are ectothermic, relying on external heat sources to maintain their body temperature at the optimum level for correct function of all body systems. Metabolism of substances and activity of the immune system are, thus, critically dependent on the body temperature. Therefore, the veterinarian must be aware of the correct temperature requirements of the respective reptile species and the hydration status of the individual patient. Furthermore, it has to be considered that large differences exist in the pharmacokinetic behaviour of enrofloxacin among different species, which additionally will influence the decision about the correct dosage of "product name (to be completed nationally)". Therefore, the recommendations made here can only be used as a starting point for individual dose setting.

5–10 mg/kg bw, corresponding to 0.2–0.4 ml/kg bw, once daily by intramuscular injection for 5 consecutive days.

An extension of the treatment interval to 48 hours may be necessary in individual cases. In complicated infections, higher dosages and longer treatment courses

may be necessary. The presence of the renal portal system in reptiles means it is prudent to administer substances in the front half of the body wherever possible.

Ornamental birds:

20 mg/kg bw, corresponding to 0.8 ml/kg bw, once daily by intramuscular injection for 5 to 10 consecutive days. In case of complicated infections higher doses may be necessary.

9. Advice on correct administration

Repeated injections should be made at different injection sites.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

10. Withdrawal periods

Pigs:

Meat and offal: 13 days.

Rabbits:

Meat and offal: 6 days.

Do not use in birds intended for human consumption.

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 vial after Exp. The expiry date refers to the last day of that month.

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

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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 52127/5119

Pack-sizes:

50 ml and 100 ml in a cardboard box.

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.

16. Contact details

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

Elanco GMBH.
Heinz-Lohmann Strasse 4
Groden
27472 Cuxhaven
Germany.

Manufacturer responsible for batch release:

KVP Pharma + Veterinär Produkte GmbH Projensdorfer Straße 324, 24106 Kiel
Germany

17. Other information

POM-V ('Veterinary medicinal product subject to prescription')

Gavin Hall

Approved: 13 April 2026