

PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril 50 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Enrofloxacin 50 mg/ml.

3. PACKAGE SIZE

50 ml,
100 ml.

4. TARGET SPECIES

Cattle (calves), sheep, goats, pigs, dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

i.m., s.c.

Read the package leaflet before use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle:

Meat and offal:

s.c.: 12 days

i.v.: 5 days

Milk: Not authorised for use in animals producing milk for human consumption.

Sheep:

Meat and offal: 4 days.

Milk: 3 days.

Goats:

Meat and offal: 6 days.

Milk: 4 days.

Pigs:

Meat and offal: 13 days.

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 52127/5120

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 50 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Enrofloxacin 50 mg/ml.

3. TARGET SPECIES

Cattle (calves), sheep, goats, pigs, dogs and cats.

4. ROUTES OF ADMINISTRATION

IV SC IM

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle:

Meat and offal:

s.c.: 12 days

i.v.: 5 days

Milk: Not authorised for use in animals producing milk for human consumption.

Sheep:

Meat and offal: 4 days.

Milk: 3 days.

Goats:

Meat and offal: 6 days.

Milk: 4 days.

Pigs:

Meat and offal: 13 days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

Once broached use by ...

Revised: April 2026
AN: 04056/2024

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 50 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 50 mg/ml solution for injection

2. Composition

Each ml contains 50 mg enrofloxacin as active substance and 30 mg n-butyl alcohol as preservative.

Clear light-yellow solution.

3. Target species

Cattle (calves), sheep, goats, pigs, dogs and cats.

4. Indications for use

Calves

Treatment of infections of the respiratory tract caused by strains of *Mannheimia haemolytica*, *Pasteurella multocida*, and *Mycoplasma* spp. Treatment of infections of the alimentary tract caused by strains of *Escherichia coli*.

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

Treatment of acute mycoplasma-associated arthritis due to strains of *Mycoplasma bovis*.

Sheep

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

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

Treatment of mastitis caused by strains of *Staphylococcus aureus* and *Escherichia coli*.

Goats

Treatment of infections of the respiratory tract caused by strains of *Mannheimia haemolytica* and *Pasteurella multocida*.

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

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

Treatment of mastitis caused by strains of *Staphylococcus aureus* and *Escherichia coli*.

Pigs

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

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

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

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*, *Pasteurella* spp., *Bordetella* spp., *Klebsiella* spp, *Pasteurella* spp., *Proteus* spp and *Pseudomonas* spp.

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.

Do not use in growing horses because of possible deleterious damage on articular cartilage.

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. For cats weighting less than 5 kg, the dosage of 25 mg/ml is more appropriate to avoid risk of overdose (see section 3.10).

Degenerative changes of articular cartilage were observed in calves treated orally with 30 mg enrofloxacin/kg body weight during 14 days.

The use of enrofloxacin in growing lambs at the recommended dose for 15 days caused histological changes in the articular cartilage, not associated to clinical signs

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.

Revised: April 2026

AN: 04056/2024

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:

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effects but have shown evidence of foetotoxic effects at maternotoxic doses.

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.

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 overdoses 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, cattle, sheep and goats, 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

Cattle (calves), sheep, goats, pigs, dogs and cats.

Rare (1 to 10 animals / 10,000 animals treated):	Injection site inflammation ¹
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction ³ (e.g. oedema ²) Excitation Digestive tract disorders (e.g. diarrhoea) ⁴ Anaphylaxis (severe allergic reaction) Ataxia (incoordination), Seizure, Tremor

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

² In dogs, moderate and transient.

³ In calves, transient may be observed up to 14 days.

⁴ Mild and transient.

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

Intravenous (i.v.), subcutaneous (s.c.) or intramuscular (i.m.) use.

Calves

5 mg of enrofloxacin/kg body weight (bw), corresponding to 1 ml/10 kg bw, once daily for 3-5 days.

Acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis*: 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily for 5 days.

The product can be administered by slow intravenous or subcutaneous administration. Not more than 10 ml should be administered at one subcutaneous injection site.

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Commented [AS2]: Added following EU PVAR2 RtQ

Sheep and goats

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

Not more than 6 ml should be administered at one subcutaneous injection site.

Pigs

2.5 mg of enrofloxacin/kg bw, corresponding to 0.5 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 bw, corresponding to 1 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.

Dogs and cats

5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once 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.

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

Cattle:

Meat and offal:

s.c.: 12 days

i.v.: 5 days

Milk: Not authorised for use in animals producing milk for human consumption.

Sheep:

Meat and offal: 4 days.

Milk: 3 days.

Goats:

Meat and offal: 6 days.

Milk: 4 days.

Pigs:

Meat and offal: 13 days.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not refrigerate or freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the 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 52127/5120

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:

Revised: April 2026
AN: 04056/2024

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