

PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril 25 mg/ml Oral Solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance: Enrofloxacin 25 mg

3. PACKAGE SIZE

100 ml; 500 ml; 1 litre

4. TARGET SPECIES

Calves and exotic animals (small mammals, reptiles and birds).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use

Dose

Calves: 5 – 10 ml/50 kg (2.5 - 5 mg/kg bw) for 3 – 5 days.

Exotic animals: please consult the insert leaflet or data sheet before use. (This product is not suitable for use in poultry).

Medicated fluids should be made up immediately prior to provision on a daily basis. Any medicated liquid remaining 24 hours after preparation must be discarded

7. WITHDRAWAL PERIODS

Calves: Meat and offal: 8 days.

Not for use in poultry (chickens and turkeys). Not for use in exotic animals or birds intended for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 28 days.

Once diluted according to directions, use within 24 hours.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Store in a dry place.

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 52127/5160

Vm 52127/3085

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril 25 mg/ml Oral Solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance: Enrofloxacin 25 mg

3. TARGET SPECIES

For oral use in calves and exotic animals (small mammals, reptiles and birds).

4. ROUTES OF ADMINISTRATION

Oral use

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Calves: Meat and offal: 8 days.

Not for use in poultry (chickens and turkeys). Not for use in exotic animals or birds intended for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 28 days.

Once opened, use by: _____

Once diluted according to directions, use within 24 hours.

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Store in a dry place.

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 25 mg/ml Oral Solution

2. Composition

Each ml contains:

Active substance: Enrofloxacin 25 mg

Excipient: Benzyl alcohol 14 mg

Clear, aqueous solution.

3. Target species

For calves and exotic species.

4. Indications for use

The veterinary medicinal product is indicated for use in calves in the treatment of infections of the respiratory and alimentary tracts of bacterial or mycoplasmal origin (e.g. pasteurellosis, mycoplasmosis, coli-bacillosis, coli-septicaemia and salmonellosis), where clinical experience supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

The veterinary medicinal product may also be used in exotic animals (small mammals, reptiles and birds) for the treatment of bacterial infections of the respiratory and alimentary tracts where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice. Estimate dosage with care.

5. Contraindications

The veterinary medicinal product should not be used for prophylaxis.

6. Special warnings

Special precautions for safe use in the target species:

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.

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 enrofloxacin should avoid contact with the veterinary medicinal product.

The veterinary medicinal product may be irritant to skin and eyes.

Personal protective equipment consisting of impervious gloves should be worn when handling the product.

Wash any splashes from skin or eyes immediately with water. Wash hands and exposed skin after use.

Do not eat, drink or smoke whilst using the product.

Pregnancy and lactation:

In the absence of data on its use in some exotic species, caution should be used when prescribing during these periods and a careful risk/benefit assessment made.

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). The simultaneous application of substances containing aluminium or magnesium can impair the absorption of enrofloxacin.

Overdose:

In very rare cases, in exotic animals where the recommended dose has been exceeded, neurological signs (ataxia, excitation) can also occur.

Do not exceed the recommended dose. In accidental overdose there is no antidote and treatment should be symptomatic.

Major incompatibilities:

None known

7. Adverse events

Species: Cattle

Very common (> 1 animal / 10 animals treated):
Common (1 to 10 animals / 100 animals treated):
Uncommon (1 to 10 animals / 1,000 animals treated):
Rare (1 to 10 animals / 10,000 animals treated):
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Gastrointestinal disorders (e.g. Diarrhoea, Vomiting) Joint cartilage disorder Anorexia

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

Oral use

Calves

Administer via the milk, milk replacer, electrolyte solution or water. The dose rate is 2.5 mg enrofloxacin per kg bodyweight (5 ml per 50 kg) daily for 3 days. This rate may be doubled to 5 mg per kg (10 ml per 50 kg) for 5 days for salmonellosis and complicated respiratory disease.

Medicated fluids should be made up immediately prior to provision on a daily basis.

Exotic Animals

The dose rates given below are for guidance only. Veterinary surgeons are advised to contact the company prior to use to discuss the particulars of each individual case.

Small Mammals

5 mg enrofloxacin per kg bodyweight (0.2 ml per kg bodyweight) orally diluted in water, twice daily for 7 days.

Reptiles

5 mg enrofloxacin per kg bodyweight (0.2 ml per kg bodyweight) orally diluted in water, at 24-48 hour intervals for 6 days.

Birds (excluding chickens and turkeys)

10 mg enrofloxacin per kg bodyweight (0.4 ml per kg bodyweight) orally diluted in water, twice daily 7 days.

For direct administration by gavage, dilutions of 1 part product to 4 parts water are recommended. If the product is to be given via the drinking water, concentrations of between 50 and 200 ppm should be considered as suitable working dilutions; concentrations in excess of 250 ppm should be avoided as precipitation may occur. The dilution should be made on a daily basis immediately prior to provision, preferably in a glass container. The use of a 0.5 ml (100 unit) insulin syringe should be considered for the withdrawal of very small volumes of the product and to facilitate dilution prior to administration. Medicated fluids should be made up immediately prior to provision on a daily basis.

9. Advice on correct administration

Do not use the veterinary medicinal product if you notice visible signs of damage to the packaging.

10. Withdrawal periods

Calves: Meat and offal: 8 days.

Not for use in poultry (chickens and turkeys). Not for use in exotic animals or birds intended for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25°C.

Store in a dry place.

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

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

Shelf life after dilution according to directions: 24 hours.

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 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 52127/5160

Vm 52127/3085

Cardboard box with one 100ml, 500 ml or 1litre polyethylene bottle.
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

Tel: +44 3308221732
PV.GBR@elancoah.com
PV.XXI@elancoah.com

Manufacturer responsible for batch release:

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

17. Other information

POM-V

Gavin Hall
Approved: 17 November 2025