PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril 2.5% Oral Solution
Antimicrobial

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains 25 mg enrofloxacin and 14 mg benzyl alcohol as preservative.

3. PHARMACEUTICAL FORM

Oral Solution.

4. PACKAGE SIZE

100 ml; 500 ml; 1 litre.

5. TARGET SPECIES

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

6. INDICATION(S) IMPORTANT

Read package leaflet or data sheet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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.

8. WITHDRAWAL PERIOD

Calves must not be slaughtered for human consumption during treatment. Calves may be slaughtered for human consumption only after 8 days from the last treatment. Not for use in poultry (chickens and turkeys). Do not use in other animals or birds intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Warnings

Baytril 2.5% Oral Solution should not be used for prophylaxis.

Wear impervious gloves when handling the product. Wash any splashes from skin or eyes immediately with water. Wash hands and exposed skin after use.

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

10. EXPIRY DATE

Exp.:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Keep the container in the outer carton. Store in a dry place.

Following withdrawal of the first dose, use within 28 days. Discard unused material.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Please refer to the package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

UK only	**IE only**
POM-V	POM

FOR ANIMAL TREATMENT ONLY

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

KEEP OUT OF THE REACH OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

UK only
Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

IE only
Bayer Ltd
Animal Health Division
The Atrium
Blackthorn Road
Dublin 18
Ireland
Tel: 01299 9313

16. MARKETING AUTHORISATION NUMBER(S)

UK only	**IE only**
Vm 00879/4117	VPA 10021/21/1

Veterinary Medicinal Product authorised for use in the UK and IE. To be supplied only on veterinary prescription.

17. MANUFACTURER'S BATCH NUMBER

BN:

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

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril 2.5% Oral Solution
Antimicrobial

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains 25 mg enrofloxacin as active substance and 14 mg benzyl alcohol as preservative.

3. PHARMACEUTICAL FORM

Oral Solution.

4. PACKAGE SIZE

100 ml; 500 ml; 1 litre.

5. TARGET SPECIES

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

6. INDICATION(S)

IMPORTANT: Read package leaflet or data sheet before use**.**

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

Exotic animals: see enclosed leaflet.

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

8. WITHDRAWAL PERIOD

Calves must not be slaughtered for human consumption during treatment. Not for use in poultry (chickens and turkeys). Calves may be slaughtered for human consumption only after 8 days from the last treatment. Do not use in other animals or birds intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Warnings
Wear impervious gloves when handling the product. Wash any splashes from skin or eyes immediately with water. Wash hands and exposed skin after use.
Do not eat or drink or smoke whilst using the product.

10. EXPIRY DATE

Exp.:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Keep the container in the outer carton. Store in a dry place.

Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

Once broached, use by: _____

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: please refer to the package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

UK only	**IE only**
POM-V	POM

For animal treatment only

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

Keep out of reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

UK only
Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

IE only
Bayer Ltd
Animal Health Division
The Atrium
Blackthorn Road
Dublin 18
Ireland
Tel: 01299 9313

16. MARKETING AUTHORISATION NUMBER(S)

UK only	**IE only**
Vm 00879/4117	VPA 10021/21/1

Veterinary Medicinal Product authorised for use in the UK and IE. To be supplied only on veterinary prescription.

17. MANUFACTURER'S BATCH NUMBER

BN:

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

PACKAGE LEAFLET FOR: BAYTRIL 2.5% ORAL SOLUTION

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

MA Holder:
Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

Manufacturer responsible for batch release: KVP Pharma und Veterinär Produkte GmbH, Projensdorfer Str. 324, 24106 Kiel, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril 2.5% Oral Solution
Antimicrobial

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

A ready to use, clear aqueous oral solution containing 25 mg/ml enrofloxacin and 14 mg/ml benzyl alcohol as preservative.

4. INDICATION(S)

Enrofloxacin is a synthetic, broad spectrum antimicrobial, bactericidal in action and effective against a wide range of Gram positive and Gram negative bacteria as well as mycoplasmas.

Baytril 2.5% Oral Solution 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.

Baytril 2.5% Oral Solution 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.

6. ADVERSE REACTIONS

On very rare occasions, mild and transient gastrointestinal disorders, such as vomiting or diarrhoea, may be observed. As a result, anorexia may occur.

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

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.

During the period of rapid growth enrofloxacin may affect articular cartilage.

7. TARGET SPECIES

For calves and exotic species.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Calves
Baytril 2.5% Oral Solution is administered via the milk, milk replacer, electrolyte solution or water. The dose rate is 2.5 mg/kg bodyweight (5 ml per 50 kg) daily for 3 days. This rate may be doubled to 5 mg/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. The dilution should be made on a daily basis immediately prior to provision, preferably in a glass container.

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/kg bw (0.2 ml/kg bw) orally, diluted in water, twice daily for 7 days.

Reptiles: 5 mg/kg bw (0.2 ml/kg bw) orally, diluted in water at 24 – 48 hour intervals for 6 days

Birds: 10 mg/kg bw (0.4 ml/kg bw) orally, diluted in water, twice daily for 7 days.

9. ADVICE ON CORRECT ADMINISTRATION

For direct administration by gavage, dilutions of 1 part Baytril 2.5% Oral Solution 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 use of a 0.5 ml (100 unit) insulin syringe should be considered for the withdrawal of very small volumes of Baytril 2.5% Oral Solution required for dilution prior to administration.

Treatment may be initiated with Baytril 2.5% Injection and maintained with this product.

10. WITHDRAWAL PERIOD(S)

Calves must not be slaughtered for human consumption during treatment. Calves may be slaughtered for human consumption only after 8 days from the last treatment. Not for use in poultry (chickens and turkeys). Do not use other animals or birds intended for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Store
in a dry place.
Keep out of reach of children.

Following withdrawal of the first dose, use the product within 28 days.

Any medicated liquid remaining 24 hours after preparation must be discarded. When the container is broached for the first time, using the in-use shelf life which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out. The discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

This product should not be used for the treatment of poultry (chickens and turkeys). Not for use in exotic animals or birds intended for human consumption.

- Enrofloxacin may cause hypersensitivity (allergic reactions). People with known hypersensitivity to enrofloxacin or to any of the excipients should avoid contact with the veterinary medicinal product.
- The veterinary medicinal product may be irritant to skin and eyes.

Wear impervious gloves 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.

Baytril 2.5% Oral Solution should not be used for prophylaxis.
Official and local antimicrobial polices 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.

For animal treatment only.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Unused product, waste material and empty containers should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations. In the UK guidance may be obtained from the local waste regulation authority, i.e. the local office of the Environment Agency or SEPA.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2023

15. OTHER INFORMATION

The pharmacokinetics of enrofloxacin in cattle are such that both oral and parenteral administration lead to similar serum levels. Enrofloxacin possesses a high distribution volume. Tissue levels 2-3 times higher than found in the serum, have been demonstrated in laboratory animals and target species. Organs in which high levels can be expected are the lungs, liver, kidney, skin, bone and lymphatic system. Enrofloxacin also distributes into the cerebrospinal fluid, the aqueous humour and the foetus in pregnant animals. In the absence of data on the use of this product during pregnancy and lactation in some exotic species, caution should be used when prescribing during these periods and a careful risk/benefit assessment made.

Package quantities
Polythene bottles of 100 ml.

Veterinary Medicinal Product authorised for use in the UK and IE. To be supplied only on veterinary prescription.

UK Only:

Vm 00879/4117

POM-V

IE Only:

VPA 10021/21/2

POM

Prescription Only Medicine

Elanco Europe Ltd. Form 2,
Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

Bayer Limited,
Animal Health Division,
The Atrium, Blackthorn Road Dublin
18, Ireland
Tel: 01299 9313

Manufactured by: KVP Pharma + Veterinär Produkte GmbH, Projensdorfer Str. 324, D-24106 Kiel, Germany

Approved 15 September 2023