

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril Piglet Doser 0.5% Oral Solution Enrofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains 5 mg enrofloxacin and 14 mg benzyl alcohol as a preservative.

3. PHARMACEUTICAL FORM

Oral solution.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

For piglets

6. INDICATION(S)

For oral use in piglets.

IMPORTANT: Read package leaflet or data sheet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

1 pump delivers 1 ml Piglets
up to 3 kg
1 ml daily for 3 – 5 days.

Piglets 3 – 10 kg
3 ml daily for 3 – 5 days.

8. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment. Piglets may be slaughtered for human consumption only after 10 days from the last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

Baytril Piglet Doser should not be used for prophylaxis.
Enrofloxacin may cause allergic reactions in some people.
Read package leaflet for full user warnings.

10. EXPIRY DATE

Expiry date:

Once broached, use by Following withdrawal of the first dose, use within 28 days.

11. SPECIAL STORAGE CONDITIONS

Keep the bottle in the outer carton. Do not store above 25°C.

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

Disposal: Please refer to package leaflet.

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

[Distribution category]

For animal treatment only. To be supplied only on veterinary prescription.

UK only

POM-V

IE only

POM

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and 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
The Atrium, Blackthorn Road Dublin
18, Ireland
Tel: 01 2999313

16. MARKETING AUTHORISATION NUMBER(S)

UK only

Vm 00879/4124

IE only

VPA 10021/4/1

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

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

Manufactured by: 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 Piglet Doser 0.5% Oral Solution Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains 5 mg enrofloxacin and 14 mg benzyl alcohol as a preservative.

3. PHARMACEUTICAL FORM

Oral solution.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

For piglets

6. INDICATION(S)

For oral use in piglets.

IMPORTANT: Read package leaflet or data sheet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

1 pump stroke delivers 1 ml

Piglets up to 3 kg: 1 ml daily for 3 – 5 days.

Piglets 3 – 10 kg: 3 ml daily for 3 – 5 days.

8. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment. Piglets may be slaughtered for human consumption only after 10 days from the last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

Baytril Piglet Doser should not be used for prophylaxis. See package leaflet for user precautions.

10. EXPIRY DATE

Expiry Date:

Once broached, use by

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

11. SPECIAL STORAGE CONDITIONS

Keep the bottle in the outer carton. Do not store above 25°C.

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

Disposal: Please refer to package leaflet.

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

For animal treatment only. To be supplied only on veterinary prescription.

UK only

POM-V

IE only

POM

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

UK only

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Bartley Wood Business Park
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RG27 9XA
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16. MARKETING AUTHORISATION NUMBER(S)

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17. MANUFACTURER'S BATCH NUMBER

Batch No.:

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

PACKAGE LEAFLET FOR: BAYTRIL PIGLET DOSER 0.5% 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 Piglet Doser 0.5% Oral Solution Enrofloxacin

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

A ready to use aqueous clear oral solution containing 5 mg/ml enrofloxacin and 14 mg/ml benzyl alcohol as a 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.

For use in piglets for diseases of the respiratory and alimentary tracts of bacterial origin (e.g. pasteurellosis, mycoplasmosis, coli-bacillosis, coli-septicaemia and salmonellosis), and multifactorial diseases such as atrophic rhinitis and enzootic pneumonia, where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

5. CONTRAINDICATIONS

Baytril Piglet Doser should not be used for prophylaxis.

6. ADVERSE REACTIONS

Slight and transient digestive tract disorders may occur in very rare cases. Do not use enrofloxacin concomitantly with antimicrobial substances acting antagonistically to quinolones (e.g. macrolides, tetracyclines, chloramphenicol).

The simultaneous application of substances containing Aluminium or Magnesium can impair the absorption of Enrofloxacin.

7. TARGET SPECIES

Piglets.

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

Baytril Piglet Doser contents are given orally using the dosing pump. 1 pump stroke delivers 1 ml.

Give 1 ml up to 3 kg bodyweight and 3 ml up to 10 kg bodyweight daily for 3 to 5 days.

Pigs weighing more than 10 kg should be treated by Baytril 5% or 10% Injection.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Animals must not be slaughtered for human consumption during treatment. Piglets may be slaughtered for human consumption only after 10 days from the last treatment.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Following withdrawal of the first dose, use the product within 28 days.

Keep the bottle in the outer carton

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. This discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

For animal treatment only.

Keep out of sight and reach of children.

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 product.

The product may be irritating 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 while using the product.

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

Unused product, waste material or 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 are such that both oral and parenteral administration leads 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 CSF, the aqueous humour and the foetus in pregnant animals.

Package quantities

Individually packed dosing pump bottles containing 100 ml.

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

UK Only:

Vm 00879/4124

POM-V

IE Only:

VPA 10021/4/1

POM

Prescription Only Medicine

Elanco Europe Ltd.

Form 2, Bartley Way

Bartley Wood Business Park

Hook

RG27 9XA

United Kingdom

Revised: September 2023
AN: 03529/2022

Bayer Limited Animal Health
The Atrium, Blackthorn Road Dublin 18, Ireland
Tel: 012999313

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

Approved 15 September 2023

A handwritten signature in black ink, appearing to be 'M. M. M.', located below the approval date.