PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril Flavour Tablets 50 mg
Antimicrobial

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains 50 mg enrofloxacin as active substance and 12 mg of a beef flavouring.

3. PHARMACEUTICAL FORM

Tablets**.**

4. PACKAGE SIZE

100 tablets.

5. TARGET SPECIES

For dogs.

6. 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 Flavour Tablets 50 mg are indicated for use in dogs in the treatment of bacterial infections of the alimentary, respiratory and urogenital tracts, skin, secondary wound infections and otitis externa where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dogs: 1 Tablet per 10 kg bodyweight (5 mg enrofloxacin per kg bodyweight) given orally once daily or as a divided dose twice daily for 3 to 10 days with or without food. Treatment may be initiated with Baytril 5% Injection or Baytril 2.5% Injection and maintained with tablets

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Do not exceed recommended dose.

Enrofloxacin may cause allergic reactions in some people. Read package leaflet for full user warnings.

Not for use in dogs less than 1 year of age or in exceptionally large breeds of dog with a longer growth period under 18 months of age, as articular cartilage may be affected during the period of rapid growth.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

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

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

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]

For animal treatment only.

UK only	POM-V	**Ireland only**	POM

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

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

Ireland only
Bayer Ltd, Animal Health Division
The Atrium, Blackthorn Road Dublin
18, Ireland
Tel: 01 299 9313

16. MARKETING AUTHORISATION NUMBER(S)

UK only
Vm 00879/4122

Ireland only
VPA 10021/5/2

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

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

Package quantities:
Strips of 10 tablets in blister foil. This carton contains 100 tablets.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER STRIP

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril Flavour 50 mg Tablets

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Bayer logo

3. EXPIRY DATE

EXP:

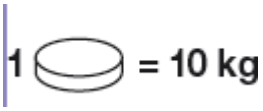
4. BATCH NUMBER

Batch No.:

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.
Keep out of the sight and reach of children.
ad.us.Vet.
50 mg
Enrofloxacin

Pictograms:



LEAFLET FOR: BAYTRIL FLAVOUR TABLETS 50 mg[1]

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 Flavour Tablets[1]
Antimicrobial

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

Light brown coloured tablets containing 15 mg, 50 mg or 150 mg enrofloxacin. The tablets contain a beef flavouring at 10% w/w, this equates to 6 mg in the 15 mg tablet, 12 mg in the 50 mg tablet and 42 mg in the 150 mg tablet.

4. INDICATIONS(S)

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 instructions given in the SPC may increase the prevalence of bacteria resistant to fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.
Official and local antimicrobial policies should be taken into account when the product is used. In cases of pyoderma, possible underlying primary disease should be identified and treated.
Enrofloxacin is partially excreted via the kidneys; as with all fluoroquinolones, excretion may therefore be delayed in individuals with existing renal damage.
The product should be used with caution in animals with severe renal or

hepatic impairment. Retinotoxic effects including blindness can occur in cats when the recommended dose is exceeded.
Enrofloxacin-containing products should not be used in animals with persisting articular cartilage growth disorders, since disorders may worsen during treatment.

Do not use in cases of known resistance to quinolones or fluoroquinolones because of near-total cross-resistance to the former and complete cross-resistance to the latter.

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 is indicated for use in dogs and cats in the treatment of bacterial infections of the alimentary, respiratory and urogenital tracts, skin, secondary wound infections and otitis externa where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice. Baytril Flavour Tablets should not be used for prophylaxis.

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1 A single package leaflet is used for all three tablets sizes

5. CONTRAINDICATIONS

Not for use in dogs less than 1 year of age or in exceptionally large breeds of dog with a longer growth period under 18 months of age, as articular cartilage may be affected during the period of rapid growth.
Not recommended for use in cats less than 8 weeks of age.

6. ADVERSE REACTIONS

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

In very rare cases, neurological signs (seizures, tremors, ataxia, excitation) and anaphylactic reactions can also occur.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 coadministration 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 Cmax of enrofloxacin.
Concurrent oral applications of substances containing calcium, aluminium or magnesium hydroxide (e.g. antacids), or multivitamins containing iron or zinc can interfere with intestinal absorption of fluoroquinolones. Enrofloxacin should therefore not be used concomitantly with those products.
The combined use of fluoroquinolones with digoxin should also be avoided because of potentially increased oral bioavailability of digoxin.

Do not exceed recommended dose. In cats retinotoxic effects including blindness can occur when the recommended dose is exceeded. In target animal studies, 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.

7. TARGET SPECIES

For cats and dogs.

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

Dogs and Cats
The dose rate of enrofloxacin is 5 mg/kg given orally once daily or as a divided dose twice daily for 3 to 10 days with or without food. Treatment may be initiated with Baytril 5% Injection or Baytril 2.5% Injection and maintained with the tablets.

The daily dose is achieved as follows:

Cats and Small Dogs
Baytril Flavour Tablets 15 mg: 1 tablet per 3 kg bodyweight.

Medium Dogs
Baytril Flavour Tablets 50 mg: 1 tablet per 10 kg bodyweight.

Large Dogs
Baytril Flavour Tablets 150 mg: 1 tablet per 30 kg bodyweight.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

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

12. SPECIAL WARNING(S)

For animal treatment only.

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. In case of contact with skin or eyes, wash the affected area with clear running water.

Wash hands after use. Keep out of the sight and reach of children.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

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 that 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 C.S.F., the aqueous humour and the foetus in pregnant animals.

Package quantities
Strips of 10 tablets in blister foil supplied in dispensing cartons containing 100 tablets.

Veterinary Medicinal Product authorised for use in the UK and IE

To be supplied only on veterinary prescription.

Marketing Authorisation Nos.

	UK	Ireland
15 mg tablets	Vm 00879/4120	VPA 10021/5/1
50 mg tablets	Vm 00879/4122	VPA 10021/5/2
150 mg tablets	Vm 00879/4121	VPA 10021/5/3

UK only

POM-V

Prescription only medicine

Ireland only

POM

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

Bayer Ltd
Animal Health Division
The Atrium, Blackthorn Road Dublin 18, Ireland
Tel 01 299 9313

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

Approved 15 September 2023