PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Card box (100 ml bottle)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril 10% Oral Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One ml of Baytril 10% Oral Solution contains:

Active substance:

Enrofloxacin	100 mg

Excipient(s):

Benzyl alcohol	14 mg.

3. PHARMACEUTICAL FORM

Solution for use in drinking water.
Clear yellowish solution.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Chicken, turkey and rabbit.

6. INDICATION(S)

Please read package leaflet carefully before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Via the drinking water. Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Chickens: Meat and offal: 3 days.
Turkeys: Meat and offal: 3 days.
Rabbits: Meat and offal: 15 days.

Not authorised for use in birds producing eggs for human consumption.
Do not administer to layer replacement birds within 14 days of coming into lay.

9. SPECIAL WARNING(S), IF NECESSARY

User safety warnings:

- Those with known hypersensitivity to (fluoro)quinolones should avoid contact with this product.
- Avoid contact with skin and eyes.
- Rinse 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.

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}
Following withdrawal of the first dose use the product within 12 weeks.
Discard unused material.
Medicated water should be made up on a daily basis. Any medicated water remaining after 24 hours after preparation must be discarded.
The date of the first withdrawal should be recorded on the label.

11. SPECIAL STORAGE CONDITIONS

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

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

For animal treatment only. 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

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

16. MARKETING AUTHORISATION NUMBER

Vm 00879/4115

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

UK Only
Vm 00879/4115
Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

POM-V

IE Only
VPA 10021/022/001
Bayer ltd,
The Atrium, Blackthorn Road,
Dublin 18
Tel: 01-2999313

POM

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle or canister

For 1000 ml bottle, please use a folded label, package leaflet information should be printed on the inside of the folded label.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril 10% Oral Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One ml of Baytril 10% Oral Solution contains:

Active substance:

Enrofloxacin	100 mg

Excipient(s):

Benzyl alcohol	14 mg.

3. PHARMACEUTICAL FORM

Solution for use in drinking water.
Clear yellowish solution.

4. PACKAGE SIZE

100 ml
500 ml
1,000 ml
5,000 ml

5. TARGET SPECIES

Chicken, turkey and rabbit.

6. INDICATION(S)

Please read package leaflet carefully before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Via the drinking water. Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Chickens: Meat and offal: 3 days.
Turkeys: Meat and offal: 3 days.
Rabbits: Meat and offal: 15 days.

Not authorised for use in birds producing eggs for human consumption.
Do not administer to layer replacement birds within 14 days of coming into lay.

9. SPECIAL WARNING(S), IF NECESSARY

User safety warnings:

- Those with known hypersensitivity to (fluoro)quinolones should avoid contact with this product.
- Avoid contact with skin and eyes.
- Rinse 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.

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}
Following withdrawal of the first dose use the product within 12 weeks.
Discard unused material.
Medicated water should be made up on a daily basis. Any medicated water remaining after 24 hours after preparation must be discarded.
The date of the first withdrawal should be recorded on the label.

11. SPECIAL STORAGE CONDITIONS

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

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

For animal treatment only. 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

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

16. MARKETING AUTHORISATION NUMBER

Vm 00879/4115

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

UK Only
Vm 00879/4115
Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

POM-V

IE Only
VPA 10021/022/001
Bayer ltd,
The Atrium, Blackthorn Road,
Dublin 18
Tel: 01-2999313

POM

PACKAGE LEAFLET FOR:
Baytril 10% Oral Solution

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

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,
The Atrium
Blackthorn Road
Dublin 18
Ireland
Tel. 01 299 9313

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril 10% Oral Solution

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

One ml of Baytril 10% Oral Solution contains:

Active substance:

Enrofloxacin 100 mg;

Excipient(s):

Benzyl alcohol 14 mg.

4. INDICATION(S)

Treatment of the respiratory tract and of the digestive tract infections caused by the following bacteria susceptible to enrofloxacin:

Chickens infected with
Mycoplasma gallisepticum,
Mycoplasma synoviae,
Avibacterium paragallinarum,
Pasteurella multocida,
Turkeys infected with
Mycoplasma gallisepticum,
Mycoplasma synoviae,
Pasteurella multocida,

Rabbits
For the treatment infectious diseases due to *Pasteurella multocida* and bacterial enteritis due to infection with *E. coli.*

Enrofloxacin should be used where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the active substance of choice.

5. CONTRAINDICATIONS

Do not use for prophylaxis.
Do not use when resistance / cross resistance to (fluoro)quinolones is known to occur.
Do not use in the case of known hypersensitivity to the active substance, other (fluoro)quinolones or to any of the excipients.

6. ADVERSE REACTIONS

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Chicken, turkey and rabbit.

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

Chickens and turkeys

10 mg enrofloxacin/kg bodyweight per day for 3–5 consecutive days.

Treatment for 3–5 consecutive days; for 5 consecutive days in mixed infections and chronic progressive forms. If no clinical improvement is achieved within 2–3 days, alternative antimicrobial therapy should be considered based on susceptibility testing.

Via the drinking water. Always make sure that the entire dose offered has been consumed. The medicated water should be made up fresh each day just before it is offered to the animals. The drinking water must be medicated throughout the treatment period, and no other water source should be available. Determine the bodyweight of the birds as accurately as possible in order to avoid underdosing.

Use only fresh pre-solutions, prepared every day before start of treatment. Pumping systems should be checked constantly to assure proper medication. Empty the water system and fill it with medicated water before starting the treatment.

Calculate the daily quantity (ml) of *“Product name”* (*to be completed nationally*) required for treatment period as follows:

Total number of birds x Average body weight in kg x 0.1 = Total volume (ml) per day

Baytril 10% Oral Solution may be put directly into the header tank or introduced via a water proportioner pump.

Rabbits

10 mg/kg bodyweight per day for 5 consecutive days.

Calculate the daily quantity (ml) of Baytril 10% Oral Solution required for treatment period as follows:

Total number of rabbits x Average body weight in kg x 0.1 = Total volume (ml) per day

9. ADVICE ON CORRECT ADMINISTRATION

For chickens and turkeys, please refer to section 8.

10. WITHDRAWAL PERIOD

Chickens: Meat and offal: 3 days.
Turkeys: Meat and offal: 3 days.
Rabbits: Meat and offal: 15 days.

Not authorised for use in birds producing eggs for human consumption.
Do not administer to layer replacement birds within 14 days of coming into lay.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the packaging.
Shelf-life after first opening the immediate packaging: 12 weeks.
The date of the first withdrawal should be recorded on the label.

12. SPECIAL WARNING(S)

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.
Since enrofloxacin was first authorised for use in poultry, there has been widespread reduction in susceptibility of *E. coli* to fluoroquinolones and emergence of resistant organisms. Resistance has also been reported in *Mycoplasma synoviae* in the EU.
Whenever possible fluoroquinolones should only be used based on susceptibility testing.
Use of the product deviating from the instructions given may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other fluoroquinolones due to the potential for cross-resistance.
Use of fluoroquinolones during the growth phase combined with a marked and prolonged increase in the intake of drinking water, and hence active ingredient, possibly due to high temperatures, may potentially be associated with damage of the articular cartilage.

No adverse clinical symptoms were observed in chickens and turkeys treated respectively with doses up to 10 and 6 times higher than the therapy dose.
In vitro, an antagonism was shown, when combining fluoroquinolones with bacteriostatic antimicrobial agents such as macrolides or tetracyclines and phenicols. The simultaneous application of substances containing aluminium or magnesium can impair the absorption of enrofloxacin.
No adverse clinical symptoms were observed in chickens and turkeys treated respectively with doses up to 10 and 6 times higher than the therapy dose.

User safety warnings:

- Those with known hypersensitivity to (fluoro)quinolones should avoid contact with this product.
- Avoid contact with skin and eyes.
- Rinse 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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

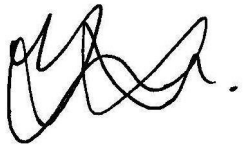
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2020

15. OTHER INFORMATION

Bottles of 100, 500 and 1,000 ml or canister of 5,000 ml.
Not all pack sizes may be marketed.

UK Only	**IE Only**
POM-VPS *Vm* 00879/4115	POM Prescription Only Medicine VPA 10021/22/001



Approved: 08 October 2020