PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril 25 mg/ml solution for injection Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One ml solution contains:
Enrofloxacin 25 mg.

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

50 ml; 100 ml.

5. TARGET SPECIES

Dogs, cats, pigs (piglets), rabbits, rodents, reptiles and ornamental birds.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Pigs:
Meat and offal: 13 days.

Rabbits
Meat and offal: 6 days.

Do not use in birds intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

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

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze.
Once broached use within 28 days.
Keep the vial in the outer carton.

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

Disposal: Read 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.

POM-V

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 00879/4118

17. MANUFACTURER'S BATCH NUMBER

Batch:

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

[Animal picotgrams] [Elanco logo]

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril 25 mg/ml solution for injection Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One ml solution contains:
Enrofloxacin 25 mg.

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

50 ml; 100 ml.

5. TARGET SPECIES

Dogs, cats, pigs (piglets), rabbits, rodents, reptiles and ornamental birds.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

SC IM
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Pigs:
Meat and offal: 13 days.

Rabbits
Meat and offal: 6 days.

Do not use in birds intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze.

Once broached use by _____

12. SPECIFIC 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 *[Distribution category]*

For animal treatment only.

POM-V

To be supplied only on veterinary prescription.

14. THE WORDS "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 00879/4118

17. MANUFACTURER'S BATCH NUMBER

Batch:

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

[Animal pictograms] [Elanco logo]

LEAFLET FOR: BAYTRIL 25 mg/ml SOLUTION FOR INJECTION

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 + Veterinär Produkte GmbH, Projensdorfer Str. 324, 24106 Kiel, Germany.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril 25 mg/ml solution for injection.

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

One ml solution container 25 mg enrofloxacin and 30 mg n-butyl alcohol as preservative.

4. INDICATION(S)

Dogs
Treatment of infections of the alimentary, respiratory and urogenital tracts (including prostatitis, adjunctive antibiotic therapy for pyometra), skin and wound infections, otitis (externa/media) caused by enrofloxacin susceptible strains of *Staphylococcus* spp*., Escherichia coli, Pasteurella* spp*., Klebsiella* spp*., Bordetella* spp*., Pseudomonas* spp*.* and *Proteus* spp*.*

Cats
Treatment of infections of the alimentary, respiratory and urogenital tracts (as adjunctive antibiotic therapy for pyometra), skin and wound infections, caused by enrofloxacin susceptible strains of: *Staphylococcus* spp*., Escherichia coli, Pasteurella* spp*., Klebsiella* spp*., Bordetella* spp*., Pseudomonas* spp*.* and *Proteus* spp*.*

Pigs (piglets)
Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mycoplasma* spp., *Actinobacillus pleuropneumoniae*.

Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli.*

Rabbits
Treatment of infections of the alimentary and respiratory tracts caused by enrofloxacin susceptible strains of: *Escherichia coli*, *Pasteurella multocida* and *Staphylococcus* spp.
Treatment of skin and wound infections caused by enrofloxacin susceptible strains of *Staphylococcus aureus.*

Rodents, reptiles and ornamental birds
Treatment of infections of the alimentary and respiratory tracts where clinical experience, if possible, supported by susceptibility testing of the causal organism, indicates enrofloxacin as the substance of choice.

5. CONTRAINDICATIONS

Do not use in the case of known hypersensitivity to fluoroquinolones or to any of the excipients.
Do not use in animals that are epileptic or suffer from seizures since enrofloxacin may cause CNS stimulation.
Do not use in young dogs during their growth, i.e. in small breeds of dogs less than 8 months of age, in big breeds of dogs less than 12 months of age, in giant breeds of dogs less than 18 months of age.
Do not use in cats less than 8 weeks of age.

6. ADVERSE REACTIONS

Digestive tract disorders (e.g. diarrhoea) may occur in very rare cases. These signs are generally mild and transient.

Local reactions at injection site
In pigs, after intramuscular administration of the product, inflammatory reactions may occur. They may persist up to 28 days after the injection.
In very rare cases, neurological signs (seizures, tremors, ataxia, excitation) and anaphylactic reactions can also occur.

In dogs, a moderate and transient local reaction (such as oedema) may occur.

In rabbits, reactions (from reddening to ulcerative lesions with deep loss of tissue), may occur. They may persist at least up to 17 days after the injection.

In reptiles and birds, muscle bruising may occur in very rare cases.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)

- very rare (less than 1 animal in 10,000 animals, including isolated reports).

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

7. TARGET SPECIES

Dogs, cats, pigs (piglets), rabbits, rodents, reptiles and ornamental birds.

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

Subcutaneous or intramuscular use.
Repeated injections should be made at different injection sites.

Dogs and cats
5 mg of enrofloxacin/kg bw, corresponding to 1 ml/5 kg bw, daily by subcutaneous injection for up to 5 days.
Treatment may be initiated with injectable product and maintained with enrofloxacin tablets. Duration of treatment should be based on the duration of treatment approved for the appropriate indication in the product information of the tablet product.

Pigs (piglets)
2.5 mg of enrofloxacin/kg bw, corresponding to 1.0 ml/10 kg bw, once daily by intramuscular injection for 3 days.

Alimentary tract infection or septicaemia caused by *Escherichia coli*: 5 mg of enrofloxacin/kg bw, corresponding to 2 ml/10 kg bw, once daily by intramuscular injection for 3 days.

In pigs, the injection should be made in the neck at the ear base.
Not more than 3 ml should be administered at one intramuscular injection site.

Rabbits
10 mg/kg bw corresponding to 2 ml/5 kg bw once daily by subcutaneous injection for 5 to 10 consecutive days.

Rodents
10 mg/kg corresponding to 0.4 ml/kg bw, once daily by subcutaneous injection for 5 to 10 consecutive days. If necessary, depending on the severity of clinical signs, this dosage can be doubled.

Reptiles

Reptiles are ectothermic, relying on external heat sources to maintain their body temperature at the optimum level for correct function of all body systems. Metabolism of substances and activity of the immune system are, thus, critically dependent on the body temperature. Therefore, the veterinarian must be aware of the correct temperature requirements of the respective reptile species and the hydration status of the individual patient. Furthermore, it has to be considered that large differences exist in the pharmacokinetic behaviour of enrofloxacin among different species, which additionally

will influence the decision about the correct dosage of Baytril 25 mg/ml solution for injection. Therefore, the recommendations made here can only be used as a starting point for individual dose setting.

5–10 mg/kg bw, corresponding to 0.2–0.4 ml/kg bw, once daily by intramuscular injection for 5 consecutive days. An extension of the treatment interval to 48 hours may be necessary in individual cases. In complicated infections, higher dosages and longer treatment courses may be necessary. The presence of the renal portal system in reptiles means it is prudent to administer substances in the front half of the body wherever possible.

Ornamental birds
20 mg/kg bw, corresponding to 0.8 ml/kg bw**,** once daily by intramuscular injection for 5 to 10 consecutive days. In case of complicated infections higher doses may be necessary.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

10. WITHDRAWAL PERIOD(S)

Pigs: Meat and offal: 13 days.

Rabbits: Meat and offal: 6 days.

Do not use in birds intended for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of sight and reach of children. Do not refrigerate or freeze. Do not use this veterinary medicinal product after the expiry date which is stated on the vial after (abbreviation used for expiry date).
Shelf life after first opening the container: 28 days.
The discard date should be recorded on the label of the glass vial after the vial was broached for the first time.

12. SPECIAL WARNING(S)

Special precautions for use in animals
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 including use deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to enrofloxacin and may decrease the effectiveness of treatment with all fluoroquinolones due to the potential for cross-resistance.

Special caution should be taken when using enrofloxacin in animals with impaired renal function.

Special caution should be taken when using enrofloxacin in cats because higher doses than recommended can cause retinal damage and blindness (see Overdose).

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 irritant to skin and eyes. In case of contact with skin or eyes, wash the affected area with clear running water.
Wash hands after use. Do not eat, drink or smoke whilst handling the product.
Care should be taken to avoid accidental self-injection. If accidental self-injection occurs, seek medical advice immediately.
Other precautions
In countries where feeding of fallen stock to scavenger bird populations is permitted as a conservation measure (see Commission Decision 2003/322/EC), the possible risk to hatching success should be considered before feeding carcasses of livestock recently treated with this product.

Pregnancy and lactation and lay
Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effects but have shown evidence of foetotoxic effects at maternotoxic doses.

Mammals
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit/risk assessment by the responsible veterinarian.

Birds and reptiles
The safety of the veterinary medicinal product has not been established during lay.
Use only according to the benefit-risk assessment by the responsible veterinarian.

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).
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 co-administration 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 C_{max} of enrofloxacin.

Overdose (symptoms, emergency procedures, antidotes)
In cases of accidental overdoses digestive tract disorders (e.g. vomiting, diarrhoea) and neurological disorders may occur.
In pigs, no adverse effects were reported after the administration of 5 times the recommended dose.
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.
In dogs, rabbits, small rodents, reptiles and birds, overdose has not been documented.
In accidental overdose there is no antidote and treatment should be symptomatic.

Incompatibilities
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2023

15. OTHER INFORMATION

Not all pack sizes may be marketed

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

UK only	IE only
POM-V	POM Prescription only medicine
Vm 00879/4118	VPA 10021/6/1

Approved 15 September 2023