

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CARTON**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Baytril 50 mg/ml solution for injection Enrofloxacin

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

One ml solution contains:

Enrofloxacin 50 mg.

**3. PHARMACEUTICAL FORM**

Solution for injection.

**4. PACKAGE SIZE**

50 ml; 100 ml.

**5. TARGET SPECIES**

Cattle (calves), sheep, goats, pigs, dogs and cats.

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

Calves:

IV: Meat and offal: 5 days. SC: Meat and offal: 12 days.

Not authorised for use in animals producing milk for human consumption.

Sheep:

Meat and offal: 4 days. Milk: 3 days.

Goats:

Meat and offal: 6 days. Milk: 4 days.

Pigs:

Meat and offal: 13 days.

## **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 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.

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 00879/4119

## **17. MANUFACTURER’S BATCH NUMBER**

Batch:

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

[Animal pictograms] [Elanco logo]

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE LABEL**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Baytril 50 mg/ml solution for injection Enrofloxacin

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

One ml solution contains: Enrofloxacin 50 mg.

**3. PHARMACEUTICAL FORM**

Solution for injection.

**4. PACKAGE SIZE**

50 ml; 100 ml.

**5. TARGET SPECIES**

Cattle (calves), sheep, goats, pigs, dogs and cats.

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

IV SC IM

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

Calves:

IV: Meat and offal: 5 days. SC: Meat and offal: 12 days.

Not authorised for use in animals producing milk for human consumption.

Sheep:

Meat and offal: 4 days. Milk: 3 days.

Goats:

Meat and offal: 6 days. Milk: 4 days.

Pigs:

Meat and offal: 13 days.

**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”**

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 00879/4119

**17. MANUFACTURER’S BATCH NUMBER**

Batch:

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

[Animal pictograms] [Elanco logo]

**PACKAGE LEAFLET FOR: BAYTRIL 50 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 50 mg/ml solution for injection

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

One ml solution contains 50 mg enrofloxacin and 30 mg n-butyl alcohol as preservative.

**4. INDICATION(S)**

**Calves**

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida*, *Mannheimia haemolytica* and *Mycoplasma* spp.

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*.

Treatment of acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis*

**Sheep**

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*.

Treatment of mastitis caused by enrofloxacin susceptible strains of *Staphylococcus aureus* and *Escherichia coli*.

### **Goats**

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida* and *Mannheimia haemolytica*.

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*.

Treatment of mastitis caused by enrofloxacin susceptible strains of *Staphylococcus aureus* and *Escherichia coli*.

### **Pigs**

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida*, *Mycoplasma* spp. and *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*.

### **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, e.g.: *Staphylococcus* spp., *Escherichia coli*, *Pasteurella* spp., *Klebsiella* spp., *Bordetella* spp., *Pseudomonas* spp. and *Proteus* spp.

## 5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to enrofloxacin or other 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.

Do not use in growing horses because of possible deleterious damage on articular cartilage.

## 6. ADVERSE REACTIONS

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

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

### Local reactions at injection site

In calves, transient local tissue reactions may occur in very rare cases and may be observed up to 14 days.

In pigs, after intramuscular administration of the product, inflammatory reactions may occur. They may persist up to 28 days after the injection.

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

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 the package leaflet, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Cattle (calves), sheep, goats, pigs, dogs, cats.

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

Intravenous, subcutaneous or intramuscular use.

Repeated injections should be made at different injection sites.

### Calves

5 mg of enrofloxacin/kg bodyweight (bw), corresponding to 1 ml/10 kg bw, once daily for 3-5 days.

Acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis*: 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily for 5 days.

The product can be administered by slow intravenous or subcutaneous administration.

Not more than 10 ml should be administered at one subcutaneous injection site.

### Sheep and goats

5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily by subcutaneous injection for 3 days.

Not more than 6 ml should be administered at one subcutaneous injection site.

### Pigs

2.5 mg of enrofloxacin/kg bw, corresponding to 0.5 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 1 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.

### Dogs and cats

5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once 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.

## **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)**

### Calves:

Following intravenous injection: Meat and offal: 5 days. Following subcutaneous injection: Meat and offal: 12 days.

Not authorised for use in animals producing milk for human consumption.

### Sheep:

Meat and offal: 4 days. Milk: 3 days.

### Goats:

Meat and offal: 6 days. Milk: 4 days.

### Pigs:

Meat and offal: 13 days.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the 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 breached 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. For cats weighing less than 5 kg, the dosage of 25 mg/ml is more appropriate to avoid risk of overdose.

Degenerative changes of articular cartilage were observed in calves treated orally with 30 mg enrofloxacin/kg body weight during 14 days.

The use of enrofloxacin in growing lambs at the recommended dose for 15 days caused histological changes in the articular cartilage, not associated to clinical signs.

#### 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.

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.

Care should be taken to avoid accidental self-injection. If accidental self-injection occurs seek medical advice immediately.

#### 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 accordingly to the benefit/risk assessment by the responsible veterinarian.

### Interaction with other medical 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, cattle, sheep and goats, 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 to 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

POM-V

Vm 00879/4119

IE only

POM

Prescription only medicine

VPA 10021/20/2

Approved 15 September 2023

