PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril 100 mg/ml solution for injection
Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One ml solution contains: Enrofloxacin 100 mg.

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

50 ml; 100 ml.

5. TARGET SPECIES

Cattle, sheep, goats and pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use

8. WITHDRAWAL PERIOD

Cattle

IV:	Meat and offal:	5 days.
	Milk:	3 days.
SC:	Meat and offal:	12 days.
	Milk:	4 days.

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 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 00879/4116

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 100 mg/ml solution for injection
Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One ml solution contains: Enrofloxacin 100 mg.

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

50 ml; 100 ml.

5. TARGET SPECIES

Cattle, sheep, goats and pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IV SC IM
Read the package leaflet before use

8. WITHDRAWAL PERIOD

Cattle

IV:	Meat and offal:	5 days.
Milk:	3 days.	
SC:	Meat and offal:	12 days.
Milk:	4 days.	

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 00879/4116

17. MANUFACTURER'S BATCH NUMBER

Batch:

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

[Animal pictograms] [Elanco logo]

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
United Kingdom
RG27 9XA

Manufacturer responsible for batch release:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril 100 mg/ml solution for injection

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

One ml solution contains 100 mg enrofloxacin and 30 mg n-butyl alcohol as preservative.

4. INDICATION(S)

Cattle
Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mannheimia haemolytica* and *Mycoplasma* spp.
Treatment of acute severe mastitis caused by enrofloxacin susceptible strains of *Escherichia coli*.
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* in cattle less than 2 years old.

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 urinary tract caused by enrofloxacin susceptible strains of *Escherichia coli.*
Treatment of post-partum dysgalactiae syndrome, PDS (MMA syndrome) caused by enrofloxacin susceptible strains of *Escherichia coli* and *Klebsiella* 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*.

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 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 intravenous treatment of cattle can cause shock reactions, presumably as a result of circulatory impairment.

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

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.

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 on this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, sheep, goats, pigs.

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

Intravenous, subcutaneous or intramuscular use.
Repeated injections should be made at difference injection sites.

Cattle
5 mg of enrofloxacin/kg body weight (bw) corresponding to 1 ml/20 kg bw, once daily for 3-5 days.

Acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis* in cattle less than 2 years old: 5 mg of enrofloxacin/kg bw corresponding to 1 ml/20 kg bw once daily for 5 days. The product can be administered by slow intravenous or subcutaneous administration.

Acute mastitis caused by *Escherichia coli*: 5 mg enrofloxacin/kg bw corresponding to 1 ml/20 kg bw by slow intravenous injection once daily for two consecutive days. The second dose may be administered by the subcutaneous route. In this case, the withdrawal period following subcutaneous injection applies.
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/20 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/20 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/20 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.

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)

Cattle
Following intravenous injection:
Meat and offal: 5 days.
Milk: 3 days.
Following subcutaneous injection:
Meat and offal: 12 days.
Milk: 4 days.

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 broached for the first time.

12. SPECIAL WARNING(S)

Special precautions for use in animals

Official and local antimicrobial polices 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.

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 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. 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

Pregnancy and lactation and lay

Cattle

The safety of the veterinary medicinal product has been established in pregnant cows during the 1st quarter of pregnancy. The product can be used in pregnant cows during the 1st quarter of pregnancy.

The use of the product in cows during the 3 last quarters of pregnancy should be based on a benefit-risk assessment by the responsible veterinarian.

The product can be used in cows during lactation.

Sheep and goats

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.

Pigs

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

The product can be used in sows during lactation.

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.

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 to 5 times the recommended dose.

In 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 that are 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 00879/4116	VPA 10021/3/1

Approved 15 September 2023