PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril Max 100 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Enrofloxacin 100 mg/ml

3. PACKAGE SIZE

100 ml

4. TARGET SPECIES

Cattle, Pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle: **s.c**. or **i.v**.
Pigs: **i.m**.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle:
Meat and offal:
s.c.: 14 days
i.v.: 7 days

Milk:
s.c.: 120 hours
i.v.: 72 hours

Pigs:
Meat and offal: **i.m**.: 12 days

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Protect from frost.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 52127/5155
Vm 52127/3080

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril Max 100 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Enrofloxacin 100 mg/ml

3. TARGET SPECIES

Cattle, Pigs.

4. ROUTES OF ADMINISTRATION

Cattle: **s.c.** or **i.v**.

Pig: **i.m.**

5. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle:
Meat and offal:
s.c.: 14 days
i.v.: 7 days

Milk:
s.c.: 120 hours
i.v.: 72 hours

Pigs:
Meat and offal: **i.m.** 12 days

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.
Once broached use by: _____

7. SPECIAL STORAGE PRECAUTIONS

Protect from frost.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Baytril Max 100 mg/ml Solution for Injection for Cattle and Pigs

2. Composition

Each ml contains:

Active substance :
Enrofloxacin 100 mg

Excipients:

n-Butanol	30 mg
Benzyl alcohol (E1519)	20 mg

Clear, yellow solution.

3. Target species

Cattle, Pigs.

4. Indications for use

Cattle:
For the treatment of respiratory tract infections caused by *Histophilus somni, Mannheimia haemolytica, Pasteurella multocida* and *Mycoplasma* spp.
For the treatment of mastitis caused by *E. coli*.

Pigs:
For the treatment of bacterial bronchopneumonia caused by *Actinobacillus pleuropneumoniae*, *Pasteurella multocida* and complicated by *Haemophilus parasuis* as a secondary pathogen in pigs.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance, other (fluoro)quinolones or to any of the excipients.
Do not use in animals with central nervous system-associated seizure disorders.
Do not use in the presence of existing disorders of cartilage development or musculoskeletal damage around functionally significant or weight-bearing joints.

6. Special warnings

Special warnings:
Cross-resistance has been shown between enrofloxacin and other (fluoro)quinolones in target pathogens, e.g. *Escherichia coli.* Use of the veterinary medicinal product

should be carefully considered when susceptibility testing has shown resistance to fluoroquinolones because its effectiveness may be reduced.

Special precautions for safe use in the target species:
For repeated injection or for injection volumes exceeding 15 ml (cattle) or 7.5 ml (pigs, calves) in divided doses, a new site must be chosen for each injection.
Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.
Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

The veterinary medicinal product should only be used in individual animals

The feeding of waste milk containing residues of enrofloxacin to calves should be avoided up to the end of the milk withdrawal period (except during the colostral phase), because it could select antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria.

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.
Use of the veterinary medicinal product deviating from the instructions given in this package leaflet may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.

Enrofloxacin is eliminated renally. As with all fluoroquinolones, delayed excretion can therefore be expected in the presence of existing renal damage.
Not for use for prophylaxis.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Direct contact with the skin should be avoided due to sensitisation, contact dermatitis and possible hypersensitivity reactions.
People with known hypersensitivity to (fluoro)quinolones should avoid contact with the veterinary medicinal product.
Wash hands after use.
In the event of accidental splash into the eye, rinse with large amounts of clean water. If irritation occurs, seek medical advice.
Do not eat, drink or smoke while handling the veterinary medicinal product.

Take care to avoid accidental self-injection.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

Antagonist effects due to concurrent administration of macrolides and tetracyclines may occur. Enrofloxacin may interfere with the metabolism of theophylline, decreasing theophylline clearance resulting in increased plasma levels of theophylline.

Overdose:
In cattle a dose of 25 mg/kg bodyweight administered by the subcutaneous route for 15 consecutive days is tolerated without any clinical symptoms. Higher doses in cattle and doses of around 25 mg/kg and above in pigs may cause lethargy, lameness, ataxia, slight salivation and muscle tremors.

Do not exceed the recommended dose. In accidental overdose there is no antidote and treatment should be symptomatic.

Major incompatibilities:

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

7. Adverse events

Cattle and pigs:

Rare (1 to 10 animals / 10,000 animals treated):	Injection site reddening[1], Injection site swelling[1] Circulatory shock[2] (Circulation failure)
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorders[3]

[1] Transitory,regress within a few days without further therapeutic measures.
[2] With intravenous treatment in cattle.
[3] In calves.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing

authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Cattle:
Subcutaneous (**s.c**.) use (respiratory disease) or Intravenous (**i.v**) use (*E. coli* mastitis).

The dosage for respiratory disease is 7.5 mg enrofloxacin per kg body weight (BW) for a single treatment by subcutaneous administration (**s.c**.).
This is equivalent to:

7.5 ml of the veterinary medicinal product per 100 kg BW and day

Do not administer more than 15 ml (cattle) or 7.5 ml (calf) per injection site (**s.c**.).
In case of serious or chronic respiratory disease a second injection may be required after 48 hours.

The dosage for the treatment of *E. coli* mastitis is 5 mg enrofloxacin per kg body weight (BW) by intravenous administration (**i.v**.).

This is equivalent to:

5 ml of the veterinary medicinal product per 100 kg BW and day

The treatment of *E. coli* mastitis should be exclusively by intravenous application on 2 to 3 consecutive days.

Pigs:
Intramuscular use (**i.m**.).
The dosage for respiratory tract infections is 7.5 mg enrofloxacin per kg body weight for a single treatment by intramuscular administration (**i.m**.) into the neck muscles behind the ear.

This is equivalent to:

0.75 ml of the veterinary medicinal product per 10 kg BW and day

Do not administer more than 7.5 ml per injection site (**i.m**.). In cases of serious or chronic respiratory disease a second injection may be required after 48 hours.

Repeated injections should be made at different injection sites.

The stopper may be safely punctured up to 20 times.

9. Advice on correct administration

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

10. Withdrawal periods

Cattle:
Meat and offal:
s.c.: 14 days
i.v.: 7 days

Milk:
s.c.: 120 hours
i.v.: 72 hours

Pigs:
Meat and offal: **i.m.** 12 days

11. Special storage precautions

Keep out of the sight and reach of children.

Protect from frost.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 52127/5155
Vm 52127/3080

Package size: 100 ml.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:

Elanco GmbH
Heinz-Lohmann Strasse 4
Groden
27472 Cuxhaven
Germany
PV.GBR@elancoah.com
PV.XXI@elancoah.com
Tel: +44 3308221732

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

17. Other information

POM-V ('Veterinary medicinal product subject to prescription')
Enrofloxacin belongs to the fluoroquinolone group of antibiotics. The mode of action of enrofloxacin is bactericidal and bactericidal activity is concentration dependent.

Enrofloxacin is active against Gram-positive and many Gram-negative bacteria such as *Histophilus somni, Mannheimia haemolytica, Pasteurella multocida, Mycoplasma* spp. and *E. coli* in cattle as well as *Actinobacillus pleuropneumoniae*, *Pasteurella multocida* and *Haemophilus parasuis* in pigs at the recommended therapeutic doses.

Gavin Hall
Approved: 17 April 2026