**PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE**

**Card box and package leaflet for brown glass bottle (Type 1)**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Enrofloxacin

## 2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:

**Active substance**:
Enrofloxacin 100 mg

**Excipients**:
n-Butanol 30 mg
Benzyl alcohol (E 1519) 20 mg

## 3. PHARMACEUTICAL FORM

Solution for injection

## 4. PACKAGE SIZE

100 ml

## 5. TARGET SPECIES

Cattle, Pig

## 6. INDICATION(S)

Read the package leaflet before use.

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

Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD (S)

Withdrawal periods:

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

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

Pig:
Meat and offal: i.m. 12 days

## 9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous - Read the package leaflet before use.

## 10. EXPIRY DATE

EXP {month/ year}
Shelf-life after first opening the immediate packaging: 28 days.
Once broached use within…

## 11. SPECIAL STORAGE CONDITIONS

Protect from frost.

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

Dispose of waste material in accordance with local requirements.

## 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 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 00879/4123

## 17. MANUFACTURER'S BATCH NUMBER

Lot {number}

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET
# Baytril Direct - 100 mg/ml solution for injection for cattle and pigs

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

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

Manufacturer responsible for the batch release:
KVP Pharma + Veterinär Produkte GmbH
Projensdorfer Str. 324
D-24106 Kiel

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Enrofloxacin

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

1 ml contains:

**Active substance**:
Enrofloxacin 100 mg

**Excipients**:
n-Butanol 30 mg
Benzyl alcohol (E 1519) 20 mg

Yellow, clear solution.

## 4. INDICATION(S)

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

Pig:

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

## 5. CONTRAINDICATIONS

Do not use for prophylaxis.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients. Do not use in known cases of resistance to other (fluoro)quinolones due to the potential for cross-resistance.

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. ADVERSE REACTIONS

In rare cases, transitory inflammatory reactions (swelling, redness) can occur at the injection site. These regress within a few days without further therapeutic measures. In rare cases, intravenous treatment can cause shock reactions in cattle, probably as a result of circulatory disturbances.
Gastrointestinal disturbances may occur in isolated cases during treatment of calves.

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 inform your veterinary surgeon.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

## 7. TARGET SPECIES

Cattle, Pig

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

Cattle:
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 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 colimastitis is 5 mg enrofloxacin per kg body weight (BW) by intravenous administration (i.v.).

This is equivalent to

**5 ml of the product per 100 kg BW and day**

The treatment of colimastitis should be exclusively by intravenous application on 2 to 3 consecutive days.

Pig:
The dosage for respiratory tract infections is 7.5 mg enrofloxacin per kg body weight for a single treatment by intramuscular administration (i.m.).

This is equivalent to

**0.75 ml of the 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.

**Method of administration:**
Repeated injections should be made at different injection sites.

Cattle:
For subcutaneous injection (respiratory disease) or for intravenous injection (colimastitis).

Pig:
For intramuscular injection into the neck muscles behind the ear.

To ensure administration of the correct dosage, body weight should be determined as accurately as possible to avoid underdosing. The stopper may be safely punctured up to 20 times.

## 9. ADVICE ON CORRECT ADMINISTRATION

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

## 10. WITHDRAWAL PERIOD

Cattle:
Meat and offal:
s.c.: 14 days
i.v.: 7 days
Milk:
s.c.: 120 hours
i.v.: 72 hours

Pig:
Meat and offal: 12 days

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of thesight and reach of children.
Protect from frost.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and label after {EXP}. The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 28 days.

## 12. SPECIAL WARNING(S)

Special precautions for use in animals:

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.
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 deviating from the instructions given in the SPC 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.

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 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 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:
May 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 (symptoms, emergency procedures, antidotes):
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.

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

Medicines should not be disposed of via wastewater. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

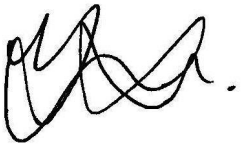
## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2020

## 15. OTHER INFORMATION

Package size: 100 ml

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



Approved: 17 September 2020