

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

Card box and bottle label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril Direct 100 mg/ml Injektionslösung für Schweine [AT]
Baytril Inject 100 mg/ml solution for injection for pigs [BE, LU, NL]
Baytril Inject – Soluzione iniettabile 100mg/ml per suini [IT]
Baytril Max 100 mg/ml solution for injection for pigs [IE, UK]

Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:

Active substance:

Enrofloxacin 100 mg

Excipients:

n-Butanol 30 mg

Benzyl alcohol 20 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Pig

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular injection. Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 12 days

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous. Read package leaflet before use.

10. EXPIRY DATE

EXP: month/ year

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

Once broached use by/.....

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 REACH AND SIGHT OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bayer plc
Animal Health Division
Bayer House
Strawberry Hill
Newbury
Berkshire
RG14 1JA

16. MARKETING AUTHORISATION NUMBER(S)
--

Vm 00010/4172

17. MANUFACTURER'S BATCH NUMBER
--

Lot {number}

PACKAGE LEAFLET
Baytril® 1inject - 100 mg/ml solution for injection for pig

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

Marketing authorisation holder:

Bayer plc
Animal Health Division
Bayer House
Strawberry Hill
Newbury
Berkshire
RG14 1JA

Manufacturer for the batch release:

KVP Pharma + Veterinär Produkte GmbH
Projensdorfer Str. 324
D-24106 Kiel

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril Direct 100 mg/ml Injektionslösung für Schweine [AT]
Baytril 1inject 100 mg/ml solution for injection for pigs [BE, LU, NL]
Baytril Inject – Soluzione iniettabile 100mg/ml per suini [IT]
Baytril Max 100 mg/ml solution for injection for pigs [IE, UK]

**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 20 mg

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance or to any of the excipients. Do not use in case of resistance against other fluoroquinolone 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. Do not use for prophylaxis.

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.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reaction(s) 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 leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pig

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

The dosage for respiratory tract infections is 7.5 mg enrofloxacin per kg body weight for a single administration. This corresponds to

0.75 ml Baytril 1nject solution for injection per 10 kg body weight per day

No more than 7.5 ml should be administered at any one injection site.

In cases of severe or chronic respiratory tract infections, a second injection may be required after 48 hours.

Method of administration:

The intramuscular injection should be made into the neck at the ear base. 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 administration of the correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

10. WITHDRAWAL PERIOD

Meat and offal: 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 carton and label 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 WARNING(S)

Special precautions for use in animals

Repeated injections should be administered at different sites.

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

People with known hypersensitivity to (fluoro)quinolones should avoid contact with the veterinary medicinal product.

Direct contact with the skin should be avoided due to sensitisation, contact dermatitis and possible hypersensitivity reactions.

Wash any splashes from skin or eyes immediately with water. Do not eat, drink or smoke while handling the product.

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:

May be used during pregnancy

Lactation:

May be used during 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):

Doses of around 25 mg active ingredient per kg body weight and above may cause lethargy, loss of appetite and ataxia. No information is available on the tolerability of doses several times higher than the therapeutic dose (over the recommended or a prolonged treatment period).

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 or household waste.

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

15. OTHER INFORMATION

Package sizes: 100 ml

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

 22 July 2016