SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril Direct 100 mg/ml Injektionslösung für Schweine [AT]
Baytril 1nject 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]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substance:
Enrofloxacin 100 mg

Excipient(s):
n-Butanol 30 mg
Benzyl alcohol (E 1519) 20 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for
injection Clear,
yellow solution

4. CLINICAL PARTICULARS

4.1 Target species

Pig

4.2 Indications for use, specifying the target species

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

4.3 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Repeated injections should be administered at different sites.
Official, national and regional 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.
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.

4.6 Adverse reactions (frequency and seriousness)

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 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)

4.7 Use during pregnancy, lactation or lay

May be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Antagonist effects due to concurrent administration of bacteriostatic antimicrobial agents such as macrolides or tetracyclines and phenicols macrolides and tetracyclines may occur.

Enrofloxacin may interfere with the metabolism of theophylline, decreasing theophylline clearance resulting in increased plasma levels of theophylline

4.9 Amounts to be administered and administration route

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.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Meat and offal: 12 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antibacterials for systemic use, Fluoroquinolones, ATCvet code: QJ01MA90

5.1 Pharmacodynamic properties

Enrofloxacin has a spectrum of activity which includes *Actinobacillus pleuropneumoniae*, *Pasteurella multocida* and *Haemophilus parasuis.*
Enrofloxacin belongs to the fluoroquinolone group of antibiotics. The substance has bactericidal activity which is mediated by binding to subunit A of DNA gyrase and the resulting selective inhibition of this enzyme.
DNA gyrase is a topoisomerase. These enzymes are involved in the replication, transcription and recombination of bacterial DNA. Fluoroquinolones also influence bacteria in the stationary phase by altering cell wall permeability.
Resistance to fluoroquinolones has been reported to arise from five sources, (i) point mutations in the
genes encoding for DNA gyrase and/or topoisomerase IV leading to alterations of the respective enzyme, (ii) alterations of drug permeability in Gram-negative bacteria, (iii) efflux mechanisms, (iv) plasmid mediated resistance and (v) gyrase protecting proteins. All mechanisms lead to a reduced susceptibility of the bacteria to fluoroquinolones. Cross-resistance within the fluoroquinolone class of antimicrobials is common.
The inhibitory and bactericidal concentrations of enrofloxacin are very close, being either identical or differing by no more than 1-2 dilution steps.

5.2 Pharmacokinetic particulars

Following intramuscular administration in pigs, the active ingredient enrofloxacin is absorbed very rapidly and almost completely (high bioavailability). Peak serum concentrations of the active ingredient are reached after 1- 2 hours.
Therapeutic concentrations are maintained for a period of at least 48 hours.
Enrofloxacin has a high volume of distribution. The concentrations in the tissues and organs mostly significantly exceed serum levels. Organs in which high concentrations can be expected include the lungs, liver, kidneys, gut and muscle tissue.
Enrofloxacin is eliminated renally.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Arginine
n-
Butanol
Benzyl alcohol (E
1519) Water for
injection

6.2 Incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product in the unopened container: 3 years Shelf life after first opening of the container: 28 days

6.4 Special precautions for storage

Protect from frost.

6.5 Nature and composition of immediate packaging

Carton box containing one 100 ml brown glass (Type 1) bottle with chlorobutyl rubber stopper secured by an aluminium crimp cap.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 00010/4172

9. DATE OF FIRST AUTHORISATION

05 September 2011

10. DATE OF REVISION OF THE TEXT

July 2016

PROHIBITION OF SALE, SUPPLY AND/OR USE

Prescription- and pharmacy-only medicine, repeat dispensing prohibited.


22 July 2016