Consumer Leaflet for a Veterinary Product

This medicine is marketed according to a veterinarian's prescription only.

For animal use only

1. Name of the veterinary medicine, form and strength

Baytril 5% injectable solution veterinary

2. Active ingredients and quantity in a single dose:

Enrofloxacin 50 mg/ml

Excipients:

Butyl alcohol: 30 mg/ml.

For the full list of excipients, see section 13 in this leaflet.

3. What is the medicine intended for

In calves:

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of Pasteurella multocida, Mannheimia haemolytica and Mycoplasma 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.

Treatment of acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of Mycoplasma bovis.

Only after the sensitivity of the bacteria has been proven and it has been found that there is no alternative treatment (proven resistance to other agents).

Therapeutic group: Fluoroquinolone antibiotic for systemic use.

4. Contra-indications

Do not use in animals with known hypersensitivity to the active ingredient enrofloxacin or other fluoroquinolones or to any of the excipients.

Do not use in animals that are epileptic or suffer from seizures since enrofloxacin may cause Central Nervous System stimulation.

5. Side effects

In very rare cases (less than 1 in 10,000 animals) digestive tract disorders (e.g. diarrhoea) may occur. These signs are generally mild and transient.

In very rare cases (less than 1 in 10,000 animals), transient local tissue injection site reactions may occur, and may be observed up to 14 days.

Side effects can be reported to the Ministry of Health by clicking on the link "Adverse Drug Reactions Report" that appears on the home page of the Ministry of Health web site (www.health.gov.il), which leads to an online form for reporting side effects. Alternatively you can use the following link: https://sideeffects.health.gov.il/

6. Target animals

Calves

7. Dosage and administration

In calves- subcutaneous use.
5 mg of enrofloxacin/kg body weight, (corresponding to 1 ml/10 kg body weight), once daily for 3-5 days.

Acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of Mycoplasma bovis: 5 mg of enrofloxacin/kg body weight, (corresponding to 1 ml/10 kg body weight), once daily for 5 days.

8. How to use the product

Subcutaneous injection - Not more than 10 ml should be administered at one subcutaneous injection site.
Repeated injections should be made at different injection sites.
To ensure a correct dosage, body weight (bw) should be determined as accurately as possible to avoid underdosing.

9. Withdrawal period- calves

Following subcutaneous injection: Meat: 12 days.
Not authorised for use in animals producing milk for human consumption.

10. Warnings

- **Special precautions for safety use in animals**

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.
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.
Special caution should be taken when using enrofloxacin in animals with impaired renal function.
Degenerative changes of articular cartilage were observed in calves treated orally with 30 mg enrofloxacin/kg body weight during 14 days.

- **Special precautions to be taken by the person administering the medicinal product to animals**

People with known hypersensitivity to fluoroquinolones should avoid any contact with the product.
Avoid skin and eye contact. Wash any splashes from skin or eyes immediately with 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 in target animals**

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effects but have shown evidence of foetotoxic effects at maternotoxic doses.

Mammals

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

- **Interaction with other medicinal 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**

In cases of accidental overdoses digestive tract disorders (e.g. vomiting, diarrhoea) and neurological disorders may occur.
In cattle, 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.

11. Storage instructions

- Avoid poisoning! This medicine, and any other medicine, must be kept in a closed place out of the reach and sight of children and/or infants to prevent accidental poisoning.
- Do not use the medicine after its expiration date (exp. date) as it appears on the package. The expiration date refers to the last day of the stated month.
- Storage conditions: Store below 25°C.
- Shelf life after the first opening of the immediate packaging: 28 days.

12. Instructions for disposing of the product / remaining product at the end of its use

Any unused veterinary medical product or any substance remaining after using the veterinary medical product must be disposed of as toxic waste; do not throw into the sewage system.

13. Additional information

- in addition to the active ingredient, this medicine also contains:

Butyl alcohol, Potassium hydroxide, Water for injections

- How does the medicine look like and what is the content of the package:

Clear yellowish solution, in a 50 ml or 100 ml brown vial, with rubber stopper and aluminum seal, packed in a carton box.
Not all pack sizes may be marketed.

- **Manufacturer name and address**: Elanco Animal Health GmbH Alfred-Nobel-Str. 50, 40789 Monheim, Germany

- **Registration holder:** Vetmarket LTD, 23 Hachoresh Way, Industrial Park Modi'in Region

- **Registration number of this medicine in the Ministry of Health State Medicine Registry:** 082-15-91819

- **Revised in** 04/2024 according to Ministry of Health instructions.