Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril flavour 25 mg/ml oral suspension for cat

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of the product contains:

Active substance:

Enrofloxacin 25 mg

Excipients:

Ascorbic acid (E300) 0.2 mg
Sorbic acid (E200) 2 mg

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral suspension

White to yellow-white suspension

4 CLINICAL PARTICULARS

4.1 Target Species

Cat

4.2 Indications for use, specifying the target species

For the treatment of single or mixed bacterial infections of the respiratory, alimentary and urinary tract, skin or wounds caused by the following enrofloxacin-sensitive Gram-negative and Gram-positive bacteria:
Staphylococci, *E. coli*, *Haemophilus* spp. and *Pasteurella* spp.

4.3 Contraindications

Do not use in

- Animals with existing impairment of cartilage growth.
- Animals with a known history of seizures, since enrofloxacin may cause CNS stimulation.
- Animals with known hypersensitivity to fluoroquinolones or any of the excipients.

For use in pregnant animals see section 4.7 and for interactions with other medicinal products see section 4.8

4.4 Special warnings for each target species

Do not use in cases of known resistance to quinolones because of near-total cross-resistance with these compounds and complete cross-resistance with other fluoroquinolones.

In animals where product administration is associated with excessive salivation or where difficulty administering the required dose is experienced, administration should be discontinued and an alternative therapy used.

4.5 Special precautions for use

Special precautions for use in animals

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 instructions given in the SPC may increase the prevalence of bacteria resistant to fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.
Official and local antimicrobial policies should be taken into account when the product is used.

Enrofloxacin is partially excreted via the kidneys; as with all fluoroquinolones, excretion may therefore be delayed in individuals with existing renal damage.

The product should be used with caution in animals with severe renal or hepatic impairment. Retinotoxic effects including irreversible blindness can occur in cats when the recommended dose is exceeded.
The safety of enrofloxacin in kittens weighing less than 0.5 kg or under 8 weeks of age has not been established.

See also section 4.3 for contraindications.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental ingestion, seek medical advice immediately and show the package leaflet to the physician.

Wash hands after use.
Wash any splashes from skin or eyes immediately with water. Do not eat, drink or smoke while handling the product.
People with known hypersensitivity to fluoroquinolones should avoid contact with the veterinary medicinal product.

4.6 Adverse reactions (frequency and seriousness)

In rare cases mild digestive tract disorders e.g. anorexia, vomiting or diarrhoea may occur. This effect usually disappears spontaneously and treatment normally does not have to be stopped. Hypersalivation may occur following administration of the product.

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

Use during pregnancy:
Studies in laboratory animals (rat, chinchilla) have not produced any evidence of a teratogenic, foetotoxic, maternototoxic effect. As the safety has not been assessed in pregnant queens, use only according to the benefit/risk assessment by the responsible veterinarian.

Use during lactation:
As enrofloxacin passes into the maternal milk, the use is not recommended during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Combination of the product (enrofloxacin) with chloramphenicol, macrolide antibiotics or tetracyclines may produce antagonistic effects.

The concomitant administration of substances containing magnesium or aluminium may reduce the absorption of enrofloxacin. These drugs should be administered two hours apart.

Concomitant administration of theophylline requires careful monitoring as serum levels of theophylline may increase.

Further, concomitant administration of fluoroquinolones in combination with non-steroidal anti-inflammatory drugs (NSAID´s) in animals could lead to seizures because of potential pharmacodynamic interactions in the CNS.

4.9 Amounts to be administered and administration route

For oral use in cats.

The product should not be administered in the animal`s feed.

The dosage is 5 mg enrofloxacin per kg bodyweight (BW) once daily.

This is equivalent to 0.2 ml per kg bodyweight once daily.

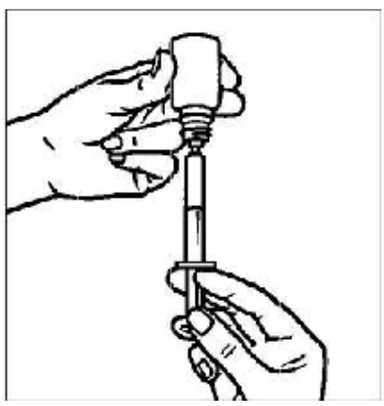
Treatment is generally given for 5 - 10 consecutive days.

Treatment should be reconsidered if no improvement of the condition is observed after 3 days of treatment.

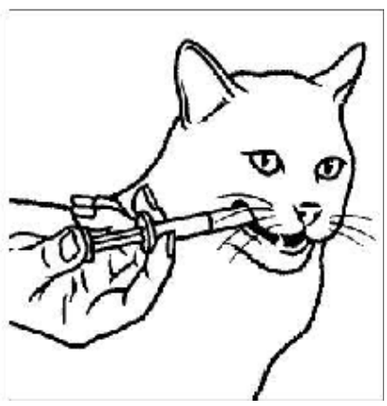
To ensure a correct dosage bodyweight should be determined as accurately as possible to avoid over- or underdosing. Do not exceed the recommended dosage.

Figure 1: Administration of the product

Shake well for 15 seconds before use



Draw out the appropriate dosage into the syringe.



Administer directly onto the back of the tongue.

In order to avoid cross-contamination, the same syringe should not be used for different animals. Thus, one syringe should only be used for one animal. After administration the syringe should be cleaned with tap water and stored in the carton box together with the product.

A 3 ml syringe with 0.1 ml graduations is supplied with every 8.5 ml and 15 ml package of the product.
For cats weighing less than 2 kg a commercially available 1 ml single dose fine dosage syringe with 0.01 ml graduations should be used.

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

In the event of extensive overdosing the first symptoms to be expected are loss of appetite and vomiting. To reduce the absorption of enrofloxacin taken orally the administration of antacids containing magnesium or aluminium is recommended.

In very rare cases diarrhoea or CNS symptoms (muscle tremor, incoordination and convulsions) may occur after administration of the product which may require treatment discontinuation.

Retinotoxic effects including irreversible blindness can occur in cats when the recommended dose is exceeded by 2-4 times and above.

4.11 Withdrawal Period(s)

Not applicable

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Fluoroquinolones
ATCvet code: QJ01MA90

5.1 Pharmacodynamic properties

Enrofloxacin is a member of the fluoroquinolone class of chemical compounds. The substance has bactericidal activity, which is the result of its binding to the A-subunit of bacterial DNA gyrase, thereby selectively inhibiting that enzyme. DNA gyrase belongs to a class of enzymes known as topoisomerases, which are involved in the replication, transcription and recombination of bacterial DNA. Fluoroquinolones also control bacteria in the stationary phase by altering the permeability of the bacterial cell wall.
Enrofloxacin exerts a concentration-dependent bactericidal action with similar values for minimal inhibitory concentration and minimal bactericidal concentrations.
Enrofloxacin has antimicrobial activity against the following enrofloxacin-sensitive Gram-negative and Gram-positive bacteria: Staphylococci, *E. coli, Haemophilus* spp. and *Pasteurella* spp.

Induction of resistance against quinolones can develop by mutations in the gyrase gene of bacteria and by changes in cell permeability towards quinolones. Both mechanisms result in decreased susceptibility of bacteria to fluoroquinolones.
The Clinical and Laboratory Standards Institute (CLSI) has established veterinary breakpoints for enrofloxacin to enable internationally harmonized evaluation of MIC data.
For cats CLSI has established the breakpoint for resistance at ≥ 4 µg/mL for dermal infections.

5.2 Pharmacokinetic properties

After administration of the product at a single oral dose of 5 mg enrofloxacin per kg body weight to cats, maximum serum levels of approximately 2.2 µg/mL are reached within 1 hour. Other studies with enrofloxacin showed an overall high oral availability of >80 %. A distribution volume of over 2 L/kg indicates good tissue penetration of enrofloxacin, with high concentrations being found in major organs, including the skin, urine, cerebrospinal fluid and bile. The tissue concentrations often exceed serum concentrations. In general fluoroquinolones tend to accumulate in macrophages and neutrophils. Protein binding in serum is 40 %. Enrofloxacin is partially metabolized to the active substance ciprofloxacin. Both active substances are partially eliminated via the kidney. Terminal half-life of enrofloxacin is approximately 7 hours.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbic acid (E200)
Ascorbic acid (E300)
Polacrilin
Dispersible cellulose (Microcrystalline Cellulose and Carmellose Sodium)
Propylene glycol (E1520)
Vanilla flavour
Purified water

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 as packaged for sale: 3 years.

Shelf-life after first opening the immediate packaging: 3 months.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

8.5 ml package: high density polyethylene bottle with a polyethylene insert, a child resistant closure and a 3 ml polypropylene oral dosing syringe with 0.1 ml graduations

15 ml package: high density polyethylene bottle with a polyethylene insert, a child resistant closure and a 3 ml polypropylene oral dosing syringe with 0.1 ml graduations

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Bayer Limited
Animal Health Division
The Atrium
Blackthorn Road
Dublin 18
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10021/061/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th August 2011
Date of last renewal: 26th May 2016

10 DATE OF REVISION OF THE TEXT