### **NOAH Compendium**

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Date: Thursday, October 31, 2019 15:11

### **Baytril Flavour Tablets**

Species: Cats, Dogs

Therapeutic indication:Pharmaceuticals: Antimicrobials: Oral

preparations: Tablets

Active ingredient: Enrofloxacin

Product: Baytril® Flavour Tablets 15 mg

Baytril® Flavour Tablets 50 mg

Baytril® Flavour Tablets 150 mg

Product index: Baytril Flavour Tablets

Incorporating: Baytril Flavour Tablets 15 mg

Baytril Flavour Tablets 50 mg

Baytril Flavour Tablets 150 mg

#### Presentation

Baytril Flavour Tablets 15 mg are light brown to brown, slightly marbled, round, planar, tablets containing 15 mg enrofloxacin and 6 mg artificial beef flavour irradiated for oral administration to dogs and cats.

Baytril Flavour Tablets 50 mg and 150 mg are light brown to brown, slightly marbled, round, curved, scored, tablets containing 50 mg or 150 mg enrofloxacin and 12 mg or 42 mg artificial beef flavour irradiated respectively for oral administration to dogs.

#### Uses

#### **Baytril Flavour Tablets 15 mg**

The product is for use in dogs and cats in the treatment of bacterial infections of the alimentary, respiratory and urogenital tracts, skin, secondary wound infections and otitis externa where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

### Baytril Flavour Tablets 50 mg and 150 mg

The product is for use in dogs in the treatment of bacterial infections of the alimentary, respiratory and urogenital tracts, skin, secondary wound infections and otitis externa where clinical experience, supported where possible by sensitivity testing of the causal

organism, indicates enrofloxacin as the drug of choice.

### **Dosage and administration**

# Dogs and cats

The dosage rate of enrofloxacin is 5 mg/kg given orally once daily or as a divided dose twice daily for 3 to 10 days with or without food. Treatment may be initiated with Baytril 5% Injection or Baytril 2.5% Injection and maintained with Baytril Flavour Tablets.

The daily dose is achieved as follows:

Cats and small dogs: 1 Baytril Flavour Tablet 15 mg per 3 kg bodyweight

Medium dogs: 1 tablet Baytril Flavour Tablets 50 mg per 10 kg bodyweight

Large dogs: 1 tablet Baytril Flavour Tablets 150 mg per 30 kg bodyweight

## Use during pregnancy and lactation

The product may be used safely in pregnant and lactating animals.

## Contra-indications, warnings, etc

Baytril Flavour Tablets should not be used for prophylaxis.

Not for use in dogs less than 1 year of age or in exceptionally large breeds of dog with a longer growth period under 18 months of age, as articular cartilage may be affected during the period of rapid growth.

Not recommended for use in cats less than 8 weeks of age.

Do not exceed the recommended dose. In accidental overdose, vomiting, diarrhoea, and CNS/behavioural changes may occur. There is no antidote and treatment should be symptomatic.

Cats: Retinotoxic effects including blindness can occur when the recommended dose is exceeded.

In target animal studies, cats have been shown to suffer ocular damage after receiving doses of more than 15 mg/kg once daily for 21 consecutive days. Doses of 30 mg/kg given once daily for 21 consecutive days have been shown to cause irreversible ocular damage. At 50 mg/kg given once daily for 21 consecutive days, blindness can occur.

Dogs: In dogs enrofloxacin may affect articular cartilage during the period of rapid growth.

#### **Environmental safety**

Any unused product or waste material should be disposed of in accordance with national requirements.

## **Pharmaceutical precautions**

Do not store above 25°C. Store in a dry place.

Shelf-life as packaged for sale: 5 years

#### Further information

Enrofloxacin is a synthetic, broad spectrum antimicrobial substance, belonging to the fluoroquinolone group of antibiotics. ATC Vet Code: QJ01MA90.

Enrofloxacin is bactericidal in action with activity against Gram positive and Gram negative bacteria and mycoplasmas. The mechanism of action of the quinolones is unique among antimicrobials – they act primarily to inhibit bacterial DNA gyrase, an enzyme responsible for controlling the supercoiling of bacterial DNA during replication. Resealing of the double standard helix is inhibited resulting in irreversible degradation of the chromosomal DNA. The fluoroquinolones also possess activity against bacteria in the stationary phase by an alteration of the permeability of the outer membrane phospholipid cell wall.

The pharmacokinetics of enrofloxacin are such that oral and parenteral administration lead to similar serum levels. Enrofloxacin possesses a high distribution volume. Tissue levels 2–3 times higher than that found in the serum have been demonstrated in laboratory animals and target species. Organs in which high levels can be expected are the lungs, liver, kidney, skin, bone, and lymphatic system. Enrofloxacin also distributes into the cerebrospinal fluid, the aqueous humour, and the foetus in pregnant animals.

# Legal category

Legal category:POM-V

## Packaging quantities

Baytril Flavour Tablets 15mg: Silver or white coloured aluminium foil blister or plastic coated aluminium blister strips of 10 light brown unmarked tablets supplied in dispensing cartons containing 100 tablets.

Baytril Flavour Tablets 50 mg and 150 mg: Silver or white coloured aluminium foil blister or plastic coated aluminium blister strips of 10 light brown to brown, scored tablets supplied in dispensing cartons containing 100 tablets.

### **Marketing Authorisation Number**

Baytril Flavour Tablets 15 mg Vm 00010/4081 Baytril Flavour Tablets 50 mg Vm 00010/4082 Baytril Flavour Tablets 150 mg Vm 00010/4083

#### Significant changes

**GTIN** 

**GTIN description:**Baytril Flavour Tablets 15mg (100 Tablets)

GTIN:05032756180014

**GTIN description:**Baytril Flavour Tablets 50 mg (100 Tablets)

**GTIN:**05032756280011

GTIN description: Baytril Flavour Tablets 150 mg (100 Tablets)

**GTIN:**05032756380018

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