Baytril 2.5% Solution for Injection

Introduction

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Presentation

A ready to use sterile aqueous injectable solution containing 25 mg/ml enrofloxacin and 30 mg/ml n-butyl alcohol as a preservative.

Uses

Enrofloxacin is a synthetic, broad spectrum antimicrobial substance, belonging to the fluoroquinolone group of antibiotics. It is bactericidal in action with activity against many gram positive and gram negative bacteria and mycoplasmas.

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.

The product may also be used in exotic animals (small mammals, reptiles and avian species) for the treatment of bacterial infections of the alimentary and respiratory tracts 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

1 ml of product per 5 kg bodyweight (5 mg enrofloxacin per kg bodyweight) by subcutaneous injection once daily for 3 to 5 days. Treatment may be initiated with the injection and maintained orally with Baytril Flavour Tablets.

Exotic animals

See Table 1.

The dose rates given below are for guidance only. Veterinary surgeons are advised to contact the company prior to use to discuss the particulars of each individual case. The use of a 0.5 ml (100 unit) insulin syringe should be considered for administration of the very small volumes required by some species of small mammals (mice, gerbils etc).

Table 1: Dosage for Baytril 2.5% Solution for Injection

<table>
<thead>
<tr>
<th>Species</th>
<th>Dosage</th>
<th>Route</th>
<th>Dose Frequency</th>
<th>Treatment period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small mammals</td>
<td>5 mg/kg bw (0.2 ml/kg)</td>
<td>s.c.</td>
<td>Twice daily</td>
<td>7 days</td>
</tr>
<tr>
<td>Reptiles</td>
<td>5 mg/kg bw (0.2 ml/kg)</td>
<td>i.m.</td>
<td>24-48 hour intervals</td>
<td>6 days</td>
</tr>
<tr>
<td>Avian spp</td>
<td>10 mg/kg bw (0.4 ml/kg)</td>
<td>i.m.</td>
<td>Twice daily</td>
<td>7 days</td>
</tr>
</tbody>
</table>

Treatment may be initiated with the injection and maintained with Baytril 2.5% Oral Solution.

Use during pregnancy and lactation

There is no restriction on the use of this product during pregnancy and lactation of the bitch and queen.

In the absence of data on its use in some exotic species, caution should be used when prescribing during these periods and a careful risk/benefit assessment made.

Contra-indications, warnings, etc

Not for use in dogs less than one year of age or in exceptionally large breeds of dog with a longer growth period under 18 months of age.

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

Baytril 2.5% Injection should not be used for prophylaxis.

Dogs: 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.
In dogs enrofloxacin may affect articular cartilage during the period of rapid growth. Occasionally skin reactions have been seen after administration to kennelled greyhounds. Exotic animals: Muscle bruising after injection in reptiles and birds has been reported occasionally.

Do not exceed the recommended dosage.

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

Not for use in exotic animals or birds intended for human consumption.

User safety:
Baytril 2.5% Solution for Injection is an alkaline solution. Wash any splashes from skin or eyes immediately with water.
Do not eat, drink or smoke whilst using the product.
Care should be taken to avoid accidental self-injection. If accidental injection occurs, seek medical advice immediately.

Pharmaceutical precautions
Do not store above 25°C.
Following withdrawal of the first dose, use the product within 28 days. Discard unused material.
Any unused product or waste material should be disposed of in accordance with national requirements.

Further information
Enrofloxacin is a synthetic, broad spectrum antimicrobial substance, belonging to the fluoroquinolone group of antibiotics. 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 stranded 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 in dogs and cats are such that oral and parenteral administration leads 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
POM-V (previously POM)

Packaging Quantities
50 ml amber type II glass vials with a grey teflonised butyl rubber stopper or a chlorobutyl PTFE stopper.

Marketing authorisation number
Vm 00010/4075.