

LEGEND KEY Template: PI_148x210mm_Kiel_v2a

Text Free Area Print Free Area Variable Data and Code area

50 mm Rule Bar

Flanco Template Key v3

[FRONT PAGE](#)

148 mm

75 mm

Pharmacode
Read Direction

210 mm

Baytril.TM
flavour

Tablets
150 mg

Tablets

150 mg

Antimicrobial

For Large Dogs

Product Description

Baytril Flavour Tablets 150 mg is a light brown to brown, slightly marbled, round and planar tablet. Each tablet contains 150 mg of enrofloxacin.

Pharmacodynamics

Enrofloxacin is a member of the fluoroquinolone class of chemical compounds. It has bactericidal activity which is mediated via a bond to the A-subunit of bacterial DNA gyrase and the resulting selective inhibition of this enzyme. DNA gyrase is a topoisomerase, a group of enzymes that are involved in the replication, transcription and recombination of DNA in bacteria. Fluoroquinolones also influence bacteria in the resting phase by altering cell wall permeability. These mechanisms explain why the viability of bacteria declines rapidly under the influence of enrofloxacin. The inhibitory and bactericidal concentrations of enrofloxacin are close together. They are either identical or only one or two dilution steps apart. Enrofloxacin is effective against most gram-negative bacteria, many gram-positive bacteria and mycoplasmas at low concentrations.

Pharmacokinetics

Administration of enrofloxacin leads to comparable serum levels after both oral (Baytril tablets) and subcutaneous administration. Peak serum concentrations of the active ingredient in serum and tissue are reached within one to two hours after administration (oral or subcutaneous) of 5 mg/kg body weight. Enrofloxacin has a high distribution volume. Concentrations in tissues and organs are usually significantly higher than serum concentrations. The minimum inhibitory concentration of the relevant pathogens is therefore very well covered by the antibiotic activity in the serum and target tissues. High concentrations may be expected in organs such as the lungs, liver, kidneys, bladder, prostate, uterus, skin, bones and lymphatic tissue. Enrofloxacin is partially excreted via the kidneys; as with all fluoroquinolones, excretion may therefore be delayed in individuals with existing renal damage.

Indication

90208932

Anti-infective (gyrase inhibitor from the group of fluoroquinolones) used to treat infectious diseases in dogs caused by the following Baytril-sensitive gram-negative and gram-positive bacteria: *E. coli*, *Salmonella* spp., *Pasteurella* spp., *Haemophilus* spp. and staphylococci.

In view of its spectrum of activity, Baytril can be used in single or mixed bacterial infections of the respiratory and digestive organs, the urinary tract, the skin and wounds.

Recommended Dosage

For oral administration.

1 x 5 mg enrofloxacin per kg body weight (BW) daily. This is equivalent to:

Baytril flavour 150 mg tablets

1 tablet per 30 kg body weight

Method of Administration

The tablets are administered directly or concealed in meat.

Treatment is generally given for 5–10 consecutive days.

If no clinical improvement occurs within three days a renewed sensitivity test should be undertaken and the treatment changed if necessary.

The animal's body weight should be determined as accurately as possible in order to ensure that the right dose is given and to avoid under-dosing.

Contraindication

Because of the propensity of fluoroquinolones to cause irreversible damage to articular cartilage during the growth phase, dogs under 12 months of age or dogs that are not yet fully grown should be excluded from treatment with Bavtril flavoured 150 mg tablets.

Do not use in animals with existing impairment of cartilage growth.

Pregnant and nursing bitches should not be treated.

Do not use on animals suffering from central seizure disorders as enrofloxacin can stimulate the central nervous system.

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

- Item code placement is flexible and can be moved to suit artwork

PRODUCT INFO			
BLUE #:	502168APK	Product Name:	BAYTRIL FLAV 150 MG TAB
Item Code:	90208932	Component:	LF
Product Code:	LBAH	Pack Size:	N/A
Previous Item Code	90202870		

ARTWORK INFO			
Template:	148 x 210 mm	Packaging Spec(s):	TPM_016192
Barcodes/Type:	Laetus: 0035	Add. Info:	N/A
		Minimum Core Data Point Size:	6 pt
GTIN:	N/A	Proof #	V1
		By/Date	ORT / HV / 06.05.2022

	
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ELANCO ARTWORK LEGEND v13

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148 mm

Do not use on food-producing animals. Animals known to be hypersensitive to fluoroquinolones should not be treated with enrofloxacin. Do not use in the event of known or suspected resistance to quinolones, as there is almost complete cross-resistance to other fluoroquinolones in animals resistant to quinolones. Do not administer concomitantly with tetracyclines, phenicols or macrolides as there is a risk of antagonistic effects. Do not administer prophylactically.

Warning and Precautions

Special warnings for each target species:
No information.

Special precautions for use:

Observe the official and local antibiotics guidelines when using the veterinary medicinal product. Using this drug product in a way that deviates from the conditions stipulated in the SPC can promote the prevalence of fluoroquinolone-resistant bacteria and may reduce the efficacy of treatment with other quinolones because of potential cross-resistance. Pyoderma is generally secondary to an underlying primary infection. It is advisable to identify the primary underlying cause and treat the animal accordingly.

Special precautions for use in animals:

Baytril Flavour Tablets 150 mg should only be used after prior confirmation of the diagnosis by bacteriological sensitivity testing of the causal organisms and in the presence of resistance to other antibiotics. Like all fluoroquinolones, Baytril Flavour Tablets 150 mg should not be used in trivial infections because of the potential for resistance development. Caution is required when administered the veterinary drug product to animals with severe liver or kidney damage.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Individuals with known hypersensitivity to fluoroquinolones or any of the other ingredients should avoid contact with this veterinary drug. Do not eat, drink or smoke during administration. Wash hands after use. In the event of accidental ingestion, consult a doctor immediately and show him this pack insert. Avoid contact with the eyes. In the event of contact with the eyes, rinse the affected eye immediately with plenty of water.

Interaction with other Medicaments

The elimination of theophylline may be delayed. Combinations of Baytril (enrofloxacin) with chloramphenicol, macrolide antibiotics or tetracyclines may produce antagonistic effects.

Simultaneous administration of substances containing magnesium or aluminium may impair the absorption of enrofloxacin. There is complete cross-resistance between fluoroquinolones. Concomitant administration of fluoroquinolones with non-steroidal anti-inflammatory drugs (NSAIDs), e.g. flunixin, to dogs is subject to strict veterinary supervision. Due to interactions between the two substances, the elimination half-lives can be extended which can lead to undesired drug reactions. Concomitant administration of fluoroquinolones with digoxin should be avoided due to the resulting risk of an elevated oral bioavailability of digoxin.

Pregnancy and Lactation

Pregnant and nursing bitches should not be treated.

Adverse Reactions

Gastrointestinal disorders may occur in isolated cases.

Overdose and Treatment

In the event of large overdoses, the initial symptoms are likely to be loss of appetite and vomiting. In very rare cases, diarrhoea or CNS symptoms (dilated pupils, muscle tremor, impaired coordination and convulsions) can occur after treatment, making it necessary to stop treatment. Administration of antacids containing magnesium or aluminium is recommended to decrease absorption of enrofloxacin after oral ingestion.

Withdrawal Period

Not applicable

Storage Condition

Do not store above 30°C.

Dosage Forms and packaging available

Baytril™ Flavour Tablets 150 mg is available in pack of 50 tablets per box.

Marketing Authorisation Holder:

Elanco Malaysia Sdn Bhd

Unit 5.04, Level 5 & 6, Tower Block,
The Bousteador, No. 10, Jalan PJU 7/6,
Mutiara Damansara, 47800 Petaling Jaya,
Selangor, Malaysia

Manufactured by:

KVP Pharma + Veterinär Produkte GmbH
Projensdorfer Straße 324, D-24106 Kiel,
Germany.

Date of revision: MAY 2022

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