# TiaMax10% w/w Granule

Registration No.:MAL20096019HA
Control medicine / Ubat Terkawal
Keep out of the reach of children
/Jauhi Ubat dari kanak-kanak
For animal use only

**[Brand or Product Name]** TiaMax 10% w/w Granule
**[Active substance]** Tiaumulin hydrogen fumarate
**[Name and strength of active substance(s)]**
Tiamulin Hydrogen Fumarate, 100g TiaMax 10% w/w Granule contains 10g Tiamulin Hydrogen Fumarate.
**[Dosage form]** Granules
**[Product Description]** White to light yellow free-flowing medicated granular premix
**[Pharmacodynamics/Pharmacokinetics/Environmental Properties]**
Tiamulin is a bacteriostatic semi-synthetic antibiotic belonging to the pleuromutilin group of antibiotics and acts at the ribosomal level to inhibit bacterial protein synthesis.
Tiamulin has shown a in-vitro activity against a wide range of bacteria such as *Brachyspira hyodysenteriae*, *Brachyspira pilosicoli, Lawsonia intracellularis* and *Mycoplasma spp*.
Tiamulin is bacteriostatic at therapeutic concentrations and has been shown to act at the 70S ribosome level and the primary binding site is on the 50S subunit and possibly a secondary site where the 50S and 30S subunits join. It appears to inhibit microbial protein production by producing biochemical inactive initiation complexes, which prevent elongation of the polypeptide chain.
Mechanisms responsible for resistance development in *Brachyspira spp* to the pleuromutilin class of antibiotics are considered to be based on mutations at the ribosomal target site. Clinically relevant resistance to tiamulin requires combinations of mutations around the tiamulin binding site.
Resistance to tiamulin may be associated with decreased susceptibility to other pleuromutilins.
**Pig**
Tiamulin is well absorbed in the pig (over 90%) following oral administration and widely distributed through the body. Tiamulin has been shown to concentrate in the lung, a target tissue, and also in liver, where it is metabolised and excreted (70-85%) in the bile, the remainder is excreted via the kidney (15-30%). Tiamulin which has not been absorbed or metabolized, passes down the intestines to the colon and concentrates there.
**Chicken(broiler, replacement pullet, layer/breeder)**
Tiamulin is well absorbed in chickens (70-95%) after oral administration.
Tiamulin distributes widely through the body and has been shown to concentrate in the liver and kidney (sites of excretion) and in the lung (30 times serum level). Excretion is mainly via the bile (55-65%) and kidney (15-30%) as mainly microbiologically inactive metabolites and is quite rapid, 99% of the dose within 48 hours.
**[Indication for Use]**
**Pigs**
For the treatment and prevention of swine dysentery caused by *Brachyspira hyodysenteriae.*
For the treatment of colitis caused by *Brachyspira pilosicoli.*
For the treatment of ileitis caused by *Lawsonia intracellularis.*
For the treatment of enzootic pneumonia caused by *Mycoplasma hyopneumoniae.*
**Chickens(broiler,replacement pullet, layer/breeder)**
For the treatment and prevention of chronic respiratory disease (CRD) and air sacculitis caused by *Mycoplasma gallisepticum* and *Mycoplasma synoviae.*
**[Recommended dosage]**
Calculations to achieve the correct dose rate and achieve the correct inclusion rate should be based on: - Inclusion rate (ppm) = dose rate (mg/kg bwt) x bodyweight (kg) / daily feed intake (kg).
To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.
The intake of medicated feed depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of tiamulin hydrogen fumarate has to be adjusted accordingly.
**Pigs**
(1)Treatment of Swine Dysentery caused by *B.hyodysenteriae,* treatment of Porcine Colonic Spirochaetosis (colitis) caused by *B.pilosicoli.*
Dosage: 5 - 10 mg tiamulin hydrogen fumarate/kg bodyweight daily administered for 7 to 10 consecutive days. The dosage will normally be achieved by an inclusion level of 100–200ppm tiamulin hydrogen fumarate in the finished feed provided that feed intake is unaffected.

| Amount of THF (mg/g) per premix formulation | Amount of premix formulation per one tonne of feed |
|---|---|
| 100.0 | 1–2 kg |

(2)Prevention of Swine Dysentery caused by *B.hyodysenteriae*
Dosage: 2.0mg tiamulin hydrogen fumarate/kg bodyweight daily. The dosage will normally be achieved by an inclusion level of 40ppm tiamulin hydrogen fumarate in the finished feed, providing feed intake is unaffected. Preventive medication with tiamulin should be given for 2-4 weeks.
Preventive treatment with tiamulin should only be initiated after confirmed infection with B.hyodysenteriae and then as part of a program including measures aiming to eradicate or control the infection in the herd.

| Amount of THF (mg/g) per premix formulation | Amount of premix formulation per one tonne of feed |
|---|---|
| 100.0 | 0.4 kg |

(3)Treatment of Porcine Proliferative Enteropathy (ileitis) caused by *L. Intracellularis*
Dosage: 7.5mg tiamulin hydrogen fumarate/kg bodyweight daily administered for 10 to 14 consecutive days. The dosage will normally be achieved by an inclusion level of 150ppm tiamulin hydrogen fumarate in the finished feed providing that feed intake is unaffected.

| Amount of THF (mg/g) per premix formulation | Amount of premix formulation per one tonne of feed |
|---|---|
| 100.0 | 1.5 kg |

(4)Treatment of Enzootic Pneumonia caused by *M.hyopneumoniae*
Dosage: 5.0-10.0mg tiamulin hydrogen fumarate/kg bodyweight daily administered for 7 to 10 consecutive days. The dosage will normally be achieved by an inclusion level of 100-200ppm tiamulin hydrogen fumarate in the finished feed provided that feed intake is unaffected.
Secondary infection by organisms such as *Pasteurella multocida* and *Actinobacillus pleuropneumoniae* may complicate enzootic pneumonia and require specific medication.

| Amount of THF (mg/g) per premix formulation | Amount of premix formulation per one tonne of feed |
|---|---|
| 100.0 | 1–2 kg |

**Chicken (broiler, replacement pullet, layer and breeder)**
Treatment and prevention of Chronic Respiratory Disease (CRD) caused by *M.gallisepticum* and air sacculitis and infectious synovitis caused by and *M.synoviae.*
Dosage – Treatment and prevention: 25mg tiamulin hydrogen fumarate/kg bodyweight daily administered for the period of 3 to 5 consecutive days. This is normally achieved by an inclusion level of 250-500 ppm tiamulin hydrogen fumarate in finished feed provided that feed intake is unaffected. Inclusion levels in the higher range will in most cases be needed to avoid underdosing. In fast growing birds, e.g. broiler chickens during the first 2-4 weeks of life, inclusion levels in the lower range may be sufficient.

| Amount of THF (mg/g) per premix formulation | Amount of premix formulation per one tonne of feed |
|---|---|
| 100.0 | 2.5-5 kg |

Preventive treatment with tiamulin should only be initiated after confirmed infection with *M.gallisepticum*, *M. synoviae* or *M.meleagridis* and then as an aid in the prevention strategy to reduce the clinical signs and mortality from respiratory disease in flocks where infection in ovum is likely because the disease is known to exist in the parent generation. The prevention strategy should include efforts to eliminate the infection from the parent generation.
**[Mode of administration]**
Oral
**[Contraindications]**
Animals should not receive products containing ionophores (monensin, narasin or salinomycin) during or for at least seven days before or after treatment with tiamulin. Severe growth depression or death may result.
**[Warning and precautions]**
*Special Warnings for each target species:*
In case of reduced feed intake, the inclusion levels in feed may need to be increased to achieve target dosage. Acute cases and severely diseased animals with reduced feed intake should be treated with a product of suitable formulation such as an injectable or water solution
*Special Precautions for use*
*I. Special precautions for use in animals*
It is sound clinical practice to base treatment on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of target bacteria.
*ii.Special precautions to be taken by the person administering the veterinary medicinal product to animals:*
When mixing the veterinary medicinal product and handling the medicated feed, direct contact with eyes, skin and mucous membranes should be avoided. Personal protective equipment should be worn when mixing the veterinary medicinal product or handling the medicated feed: overalls, impervious gloves and either a disposable half-mask respirator. Wash contaminated skin.
In case of accidental ingestion, seek medical advice immediately and show the package insert or label to the physician.
People with known hypersensitivity to tiarnulin should administer the product with caution.
**[Interactions with other medicaments]**
Tiamulin has been shown to interact with ionophores such as monensin, salinomycin and narasin and may result in signs indistinguishable from an ionophore toxicosis. Animals should not receive products containing monensin, salinomycin or narasin during or at least 7days before or after treatment with tiamulin. Severe growth depression, ataxia, paralysis or death may result.
If signs of an interaction do occur, administration of contaminated feed should be stopped immediately. The feed should be removed and replaced with fresh feed not containing the anticoccidials monensin, salinomycin or narasin.
**[Statement on usage during pregnancy and lactation]**
Can be used in pigs during pregnancy and lactation
Can be used in laying and breeding chickens
**[Adverse Effects/ Undesirable Effects]**
On rare occasions erythema or mild oedema of the skin may occur in pigs following the use of tiamulin.
**[Overdose and treatment]**
Pigs: Single oral doses of 100 mg/kg bodyweight in pigs caused hyperpnoea and abdominal discomfort. At 150 mg/kg no CNS effects were noted except for sedation. At 55 mg/kg given for 14 days a transient salivation and slight gastric irritation occurred. A minimum lethal dose has not been established in the pig.
Chickens: The LD5 for chickens is 1290 mg/kg bodyweight.
The clinical signs of acute toxicity in chickens are – vocalization, clonic cramps and lateral recumbency.
If signs of intoxication do occur promptly remove the medicated feed, replace with fresh unmedicated feed and apply supportive, symptomatic therapy.
**[Withdrawal period(s)]**
Pigs
Prevention (at 2.0mg/kg bwt): 1 day
Treatment (at 5-10mg/kg bwt): 6 days
Chickens(broiler,replacement pullet, layer/breeder)
Meat and offal: 1 day
Eggs: 0 days
**[Storage Conditions]** Store at 30℃ or below, protected from light.
**[Shelf life]** 2 years
**[Shelf Life after opening of container]** Once opening the container, please use the product within 24 hours.
**[Shelf Life after reconstitution]** 3 months
**[Package]** 25kg/Bag
**[Disposal of containers]** Disposal in accordance with local regulation.
**[Batch No.]**
**[Mfg. Date]**
**[Exp. Date]**

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Brighter health solutions

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