

[Package insert information will be printed on the product label]

PACKAGE INSERTS

[Brand or Product Name]: HINATIAMU 200G/KG GRANULES

[Name and Strength of Active Substance(s)]: 20% Tiamulin Hydrogen Fumarate, 100g: 20g

[Product Description]: White or almost white granule.

[Pharmacodynamics]:

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 an 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 biochemically 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.

[Pharmacokinetics]:

Tiamulin is well absorbed in the pig (over 90%) following oral administration and widely distributed throughout 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 metabolised, passes down the intestines to the colon and concentrates there.

[Indication]:

- 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*.

[Recommended Dosage]:

Mix with the feed.

1. Prevention of Swine Dysentery caused by *B. Hyodysenteriae*

Dosage: 2.0 mg tiamulin hydrogen fumarate/kg bodyweight daily. The dosage will normally be achieved by an inclusion level of 40 ppm tiamulin hydrogen fumarate in the finished feed, providing feed intake is unaffected. Preventive medication with tiamulin should be given for 2-4 weeks.

Administration: 0.2 kg (equivalent to 40 g tiamulin hydrogen fumarate) per 1 tonne of feed.

Meat withdrawal period: 1 day

2. Treatment of Swine Dysentery caused by *B. hyodysenteriae*, treatment of Porcine Colonic Spirochaetosis (colitis) caused by *B. pilosicoli*. Treatment of Enzootic Pneumonia caused by *M. Hyopneumoniae*

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 100-200 ppm tiamulin hydrogen fumarate in the finished feed provided that feed intake is unaffected.

Administration: 0.5-1.0 kg (equivalent to 100-200 g tiamulin hydrogen fumarate) per 1 tonne of feed.

Meat withdrawal period: 6 days

3. Treatment of Porcine Proliferative Enteropathy (ileitis) caused by *L. Intracellularis*.

Dosage: 7.5 mg tiamulin hydrogen fumarate/kg bodyweight daily administered for 10 to 14 consecutive days. The dosage will normally be achieved by an inclusion level of 150 ppm tiamulin hydrogen fumarate in the finished feed providing that feed intake is unaffected.

Administration: 0.75 kg (equivalent to 150 g tiamulin hydrogen fumarate) per 1 tonne of feed.

Meat withdrawal period: 6 days

[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.

[Warnings and Precautions]:

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.

When mixing the veterinary medicinal product and handling the medicated feed, direct contact with eyes, skin and mucous membranes should be avoided.

People with known hypersensitivity to tiamulin should administer the product with caution.

[Interactions with Other Medicament]:

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 7 days 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.

[Pregnancy and lactation]:

Can be used in pigs during pregnancy and lactation.

[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. If signs of intoxication do occur promptly remove the medicated feed, replace with fresh unmedicated feed and apply supportive, symptomatic therapy.

[Proposed shelf life after reconstitution]: After reconstitution in feed, use within 24 hours.

[Disposal of container]: Unused material and packaging should be disposed of in accordance with all local and national legislation.

[Storage Conditions]: Keep sealed and stored in cool and dry place below 30°C

[Dosage Forms and packaging available]: 25kg/drum

Manufactured by:

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Product Registration Holder:

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