VETMULIN® 125 mg/ml Oral Solution (tiamulin hydrogen fumarate)

COMPOSITION

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<thead>
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<th>Content</th>
<th>Vetmulin® 125 Solution</th>
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<tr>
<td>Tiamulin hydrogen fumarate</td>
<td>125 mg</td>
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<tr>
<td>Excipients</td>
<td>Up to 1 ml</td>
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The product contains as excipients: Methyl parahydroxybenzoate, propyl parahydroxybenzoate.

PHARMACOLOGICAL ACTION

Tiamulin hydrogen fumarate is a semi-synthetic derivative of the diterpene antibiotic pleuromutilin, produced by Pleurotus mutilis. Tiamulin is bacteriostatic and inhibits protein synthesis. The product has a strong affinity for the ribosome, causing an inhibition of peptidyl transferase. As a result protein synthesis is stopped. If response to treatment of dysentery with the product is poor, then the possibility of resistance must be considered. Following oral administration, tiamulin hydrogen fumarate is rapidly absorbed from the gastrointestinal tract of pigs (85-90%) and appears in the blood within 30 minutes. There is a very good distribution in the tissues with accumulation in lungs and in the colon. 30-50% of tiamulin is bound to serum proteins. Tiamulin is rapidly metabolised in the liver (hydroxylation, dealkalisation, hydrolysis).

INDICATIONS

For the treatment of Swine Dysentery caused by or further complicated by tiamulin-susceptible Brachyspira hyodysenteriae.

Treatment of Enzootic Pneumonia and the reduction of lesions caused by tiamulin-susceptible Mycoplasma hyopneumoniae.

The product can be used during pregnancy and lactation.

CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to the active ingredient.

Do not administer products containing monensin, salinomycin, narasin, maduramycin or other ionophores during or for at least seven days before or after treatment with the product.

MODE OF ADMINISTRATION

The uptake of medication by animals can be altered as a consequence of illness.

In case of insufficient uptake of water, animals should be treated parenterally.

Medicated water should be refreshed every 24 hours. The uptake of consistent amounts of drinking water should be ensured by sufficient drinking facilities. To avoid formation of resistance by consumption of tiamulin in subtherapeutic doses, the watering equipment has to be cleaned adequately at the end of treatment.

TARGET SPECIES

Pigs.
DOSAGE

Swine Dysentery
8.8 mg tiamulin hydrogen fumarate per kg body weight per day (equivalent to 7 ml product per 100 kg body weight per day) for 5 consecutive days.

Enzootic Pneumonia
15-20 mg tiamulin hydrogen fumarate per kg body weight per day (equivalent to 12-16 ml product per 100 kg body weight per day) for 5 days.

The uptake of medicated water depends on the actual body weight, the water consumption, the clinical condition of the animals, the environment, the age and the kind of feed provided. In order to obtain the correct dosage, the concentration of tiamulin should be calculated, as follows:

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\text{ml Vetmulin 125 mg/ml oral solution for use in drinking water per kg body weight per day} \times \text{Average body weight (kg)} = \text{ml Vetmulin 125 mg/ml oral solution for use in drinking water per litre of drinking water}
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To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing. The required doses should be measured by suitably calibrated measuring equipment.

SIDE EFFECTS

In rare cases, hypersensitivity to tiamulin following oral administration is reported in terms of cutaneous and genital erythema and pruritus. The adverse reactions are often mild and transient, but in very rare cases may be serious. If these typical side effects occur, stop treatment immediately and clean animals and pens with water. Normally, the animals recover fast thereafter. Symptomatic treatment such as electrolyte therapy and an anti-inflammatory therapy may be useful. If you notice any serious or other effects not mentioned in this leaflet, please inform your veterinary physician.

WITHDRAWAL PERIOD

Meat and offal: 5 (five) days.

STORAGE

Store below 25°C.

PACKING

Vetmulin® 125 mg/ml is presented in a 1 litre white high-density polyethylene bottle with white polypropylene tamper-evident closure, sealed with white foamed disk.

WARNING

People with known hypersensitivity to the active substance must not administer the veterinary medicinal product. When mixing, direct contact with the skin and mucous membranes should be avoided. Accidental ingestion should be avoided. Wear overalls, safety glasses, mask and impervious gloves when handling or mixing the product. Contaminated clothing should be removed and any splashes on to the skin should be washed off immediately. If accidental eye contact occurs, immediately rinse thoroughly with water. Seek medical advice if irritation persists. Wash hands after use.