VETMULIN® 450 mg/g Granules for use in drinking water (tiamulin hydrogen fumarate)

**COMPOSITION**

<table>
<thead>
<tr>
<th>Content</th>
<th>VETMULIN® 450 oral granules</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tiamulin hydrogen fumarate</td>
<td>450 mg</td>
</tr>
<tr>
<td>Excipients</td>
<td>Up to 1 g</td>
</tr>
</tbody>
</table>

The product contains as excipients: povidone, lactose monohydrate.

**PHARMACOLOGICAL ACTION**

Tiamulin hydrogen fumarate is a semi-synthetic diterpene antibiotic. The mode of action is by inhibition of ribosomal protein synthesis in sensitive bacteria. It is a bacteriostatic antibiotic. *In vitro* research has shown that resistant bacterial mutants can be created through multistep resistance. Development of resistance in mycoplasmas is slower. Resistance against *B. hyodysenteriae* has been seen, however this spirochete remains very sensitive to tiamulin. Cross-resistance between tiamulin and tylosin tartrate has been reported: micro-organisms that are resistant to tiamulin, are also resistant to tylosin tartrate, but not vice versa. Resistance in *Brachyspirae hyodysenteriae* can be caused by a point mutation in the 23S rRNA gene.

**INDICATIONS**

**Pigs:** For the treatment of Swine Dysentery caused by tiamulin-susceptible *Brachyspira hyodysenteriae*.
For the treatment of Enzootic Pneumonia caused by tiamulin-susceptible *Mycoplasma hyopneumoniae*.
The presence of the disease in the herd should be established before use.

**CONTRAINDICATIONS**

Do not use in animals with known hypersensitivity to the active ingredient or to any excipient. Tiamulin is known to produce clinically important – often lethal – interactions with antibiotics belonging to the ionophores. Therefore, pigs should not receive products containing monensin, narasin, salinomycin during or at least 7 days before and after treatment with the product. Tiamulin may lessen the antibacterial activity of β-lactam antibiotics whose action is dependent on bacterial growth.

**MODE OF ADMINISTRATION**

For oral administration through the drinking water. The uptake of medicated water depends on 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 has to be adjusted accordingly. Use suitably calibrated weighing equipment to weigh the necessary amount of product.

**TARGET SPECIES**

Pigs.
DOSAGE

Pigs:
Swine dysentery caused by *Brachyspira hyodysenteriae*: 8.8 mg tiamulin hydrogen fumarate per kg body weight per day for 5 consecutive days. Enzootic Pneumonia caused by *Mycoplasma hyopneumoniae* 15-20 mg tiamulin hydrogen fumarate per 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.

\[
\frac{\text{...mg Vetmulin 45% WSG per kg body weight per day}}{\text{Average body weight (kg)}} \times \text{Average daily water intake (l/animal)} = \text{... mg Vetmulin 45% WSG per litre of drinking water}
\]

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing. The product can be added directly to the required volume of drinking water or a concentrated solution can be prepared to be diluted to the final concentration afterwards. The maximum solubility of the product is 10 gram/litre. Fresh solution should be made up each day and other sources of drinking water should be prevented. Do not use rusty recipients for preparing the solutions.

To avoid formation of resistance by consumption of tiamulin in sub therapeutic doses, the watering equipment has to be cleaned adequately at the end of treatment.

If there is no response to treatment within 3 days, the diagnosis should be re-considered and treatment should be changed, if necessary. Water intake should be monitored at frequent intervals during medication.

SIDE EFFECTS

On rare occasions, hypersensitivity to tiamulin following oral administration is reported in terms of increased salivation, mild oedema, acute dermatitis with cutaneous erythema and intense pruritus. The adverse reactions are often mild and transient, but on very rare occasions may be serious and can lead to apathy or death. 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.

WITHDRAWAL PERIOD

Meat and offal: 5 (five) days.

STORAGE

Do not refrigerate or freeze. Store in original container.

PACKING

Block bottomed zipped 1 kg bag PET/ALU/LDPE.
**WARNING**

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. Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies. Strategic treatment should be limited to animals where tiamulin susceptible agents have been isolated in the herd. 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. Wash affected parts if skin contact occurs. If accidental eye contact occurs, immediately rinse thoroughly with water. Seek medical advise if irritation persists. Contaminated clothing should be removed and any splashes on to the skin should be washed off immediately.