VETMULIN® 162 mg/ml Solution for injection (tiamulin hydrogen fumarate)

**COMPOSITION**

<table>
<thead>
<tr>
<th>Content</th>
<th>VETMULIN® 162 mg/ml</th>
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<tbody>
<tr>
<td>Tiamulin hydrogen fumarate</td>
<td>162 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: Butyl parahydroxybenzoate, Ethanol (96%), Propyl gallate (E310), Sesame oil, refined.

**PHARMACOLOGICAL ACTION**

Tiamulin 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 and the following organisms show sensitivity in vitro: Brachyspira: *Brachyspira hyodysenteriae*, Mycoplasmas: *Mycoplasma hyopneumoniae*, *M. hyorhinis*, *M. hyosynoviae*, *Mycoplasma synoviae*. Gram-positive: *Staphylococcus* spp., *Streptococcus* spp., *Arcanobacterium pyogenes*. Gram-negative: *Pasteurella* spp., *Klebsiella pneumoniae*, *Actinobacillus (Haemophilus)* spp., *Fusobacterium necrophorum*, *Bacteroides* spp., *Campylobacter coli*. The mechanism of resistance is chromosomal. Appearance of resistance is slow and progressive. Following a single intramuscular administration at a dose rate of approximately 14 mg tiamulin per kg body weight, mean maximum tiamulin concentration (approximately 350 mg/ml) was reached after approximately 3 hours. The mean terminal half life is approximately 12 hours.

**INDICATIONS**

For treatment and prevention of Swine Dysentery caused by *Brachyspira hyodysenteriae*. The product is not appropriate for use for the prevention of disease at the level of herd treatment but should only be used for prevention in individual animals with a known history of exposure to diseased animals. For the treatment of Enzootic Pneumonia caused by tiamulin-susceptible *Mycoplasma hyopneumoniae* and mycoplasmal arthritis caused by tiamulin susceptible *Mycoplasma hyosynoviae*.

**CONTRAINDICATIONS**

Do not use in animals with known hypersensitivity to the active ingredient or any of the excipients. Do not use in cases of known resistance to tiamulin.

**MODE OF ADMINISTRATION**

For intramuscular use. Inflammation/scarring may occur at the site of injection. For this reason, it is recommended that the product should be administered into the muscle of the neck. The closures should not be broached more than 5 times. In order to prevent excessive broaching of the stopper, a suitable multiple dosing device should be used.

**TARGET SPECIES**

Pigs.
**DOSAGE**

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

For the treatment of clinical Swine Dysentery:

8.1 mg tiamulin base per kg body weight (equivalent to 1 ml per 20 kg body weight) to be administered in a single treatment followed by tiamulin in the water or feed. For the treatment of Enzootic Pneumonia or Mycoplasmal Arthritis: 12.1 mg tiamulin base per kg body weight (equivalent to 1.5 ml/20 kg body weight) daily for 3 consecutive days. Depending on the severity of disease it may be necessary to continue treatment by orally administered tiamulin until 2 days after signs of disease have subsided.

**SIDE EFFECTS**

In rare cases, hypersensitivity to tiamulin is reported in terms of acute dermatitis with cutaneous erythema and intense pruritus. The adverse reactions are usually mild and transient but in very rare cases may be serious. Symptomatic treatment such as electrolyte therapy and an anti-inflammatory therapy may be useful.

**WITHDRAWAL PERIOD**

Meat and offal: 21 days.

**STORAGE**

Store below 25 °C. Do not refrigerate or freeze. Protect from light.

**PACKING**

The product is presented in a 100 ml Type I amber glass vial, sealed with a nitrile rubber stopper supplied in a carton. One vial per carton.

**WARNING**

People with known hypersensitivity to tiamulin should handle the product carefully. Direct contact with the skin, eyes and mucous membranes should be avoided when handling the product. In case of accidental eye contact, irrigate the eyes thoroughly with clean running water immediately. Seek medical advice if irritation persists. In case of skin contact, wash immediately with running water in order to minimize absorption through the skin. Wash hands after use. This product contains sesame oil. Accidental self injection may result in severe localised reactions, particularly if injected into a joint or finger. In case of accidental injection, seek medical advice immediately. Show the package leaflet or the label to the physician.

Tiamulin is known to produce clinically important (often lethal) interactions with ionophore antibiotics, including monensin, narasin, salinomycin. Therefore, pigs should not receive products containing such compounds during, or for at least seven days before or after treatment with this product. Severe growth depression or death may result. Tiamulin may lessen the antibacterial activity of beta-lactam antibiotics, whose action is dependent on bacterial growth.