

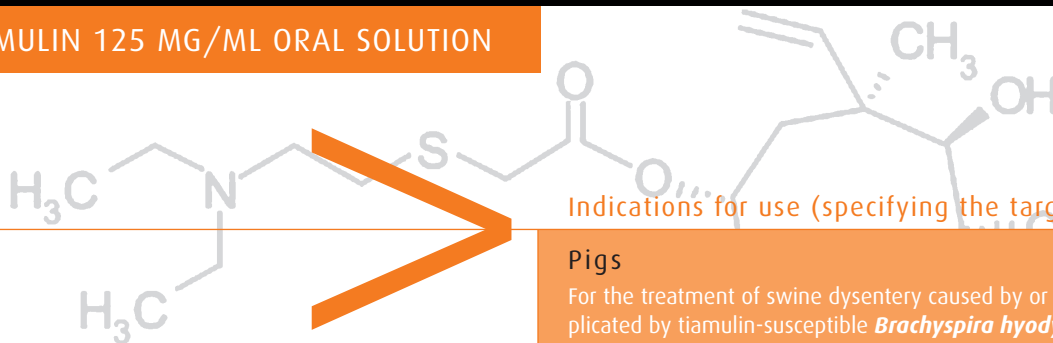


Vetmulin®

125 MG/ML ORAL SOLUTION FOR USE IN DRINKING WATER FOR PIGS



VETMULIN 125 MG/ML ORAL SOLUTION



Name of the veterinary medicinal product

Vetmulin 125 mg/ml Oral Solution for use in drinking water for pigs

Qualitative and quantitative composition

Each ml contains:

Active substance 125 mg Tiamulin hydrogen fumarate (equivalent to 101.2 mg tiamulin)

Excipients

Methyl parahydroxybenzoate (E218): 0.90 mg

Propyl parahydroxybenzoate (E216): 0.10 mg

PHARMACEUTICAL FORM

- Oral solution for use in drinking water
- Clear colourless to slightly yellow liquid

Target species

Pigs

Contraindications

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

Special precautions for use

People with known hypersensitivity to the active substance must not administer the veterinary medicinal product, direct contact with mucous membranes should be avoided. They must wear safety glasses and clothing, mask and gloves to the skin when handling and mixing the product. If accidental eye contact occurs, immediately rinse thoroughly with water.

Safety

The minimum lethal dose of tiamulin hydrogen fumarate has not been established in pigs. A single oral dose of 55 mg/kg during 14 days, increases salivation and a mild irritation of the stomach. 100 mg/kg BW causes hyperpnoea and abdominal complaints in pigs and 150 mg/kg causes lethargy on the central nervous system

Adverse reactions (frequency and seriousness)

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. Symptomatic treatment such as electrolyte therapy and an anti-inflammatory therapy may be useful.

Use during pregnancy, lactation or lay

The product can be used during pregnancy and lactation.

Indications for use (specifying the target species)

Pigs

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*.

Interaction with other medicinal products and other forms of interaction

Animals should not receive products containing monensin, salinomycin, narasin, maduramycin or other ionophores during or for at least seven days before or after treatment with the product. Severe growth depression, paralysis or death may result.

Amount(s) to be administered and administration route

For oral administration through the drinking water

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

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

Practical Administration:

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:

| | | | | |
|--|---|-----------------------------|---|---|
| ...ml Vetmulin® 125 mg/ml oral solution for use in drinking water per kg body weight and day | X | Average body weight (kg) | = | ...ml Vetmulin® 125 mg/ml oral solution for use in drinking water per litre of drinking water |
| Average daily water intake (l/animal) | | | | |

Withdrawal period(s)

Meat and offal: 5 days

Shelf-life

- Shelf-life of the veterinary medicinal product as packaged for sale 30 months
- Shelf-life after first opening the immediate packaging: 3 months
- Shelf-life after dilution according to directions: 24 hours

Special precautions for storage

Do not store above 25 °C.

Nature and composition of immediate packaging

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.

