

**PACKAGE LEAFLET**

**Vetmulin 450 mg/g** granules for use in drinking water for pigs (All MS except FR)  
Vetmulin 364 mg/g granules for use in drinking water for pigs (FR only)  
tiamulin

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**Marketing authorisation

Huvepharma NV, Uitbreidingstraat 80, 2600 Antwerpen, Belgium

Manufacturer

Biovet JSC, 39 Petar Rakov Str, 4550 Peshtera - Bulgaria

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

**Vetmulin 450 mg/g** granules for use in drinking water for pigs.  
Tiamulin hydrogen fumarate

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**

Each gram contains Tiamulin hydrogen fumarate 450.0 mg (equivalent to tiamulin 364.2 mg)

White to pale yellow granules

**4. INDICATION(S)**

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..

**5. CONTRAINDICATIONS**

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

Do not use in case of resistance to tiamulin.

Do not administer products containing ionophores such as monensin, salinomycin or narasin during or for at least 7 days before or after treatment with the product.

## 6. ADVERSE REACTIONS

In rare cases, 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.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Pigs

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral administration through the drinking water.

Swine dysentery caused by *Brachyspira hyodysenteriae*:  
is 8.8 mg tiamulin hydrogen fumarate per kg bodyweight per day for 5 consecutive days.

Enzootic pneumonia caused by *Mycoplasma hyopneumoniae*  
15-20 mg tiamulin hydrogen fumarate per kg bodyweight per day for 5 days.  
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/liter.

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.

## 9. ADVICE ON CORRECT ADMINISTRATION

Use suitably calibrated weighing equipment to weigh the necessary amount of product .

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:

$$\frac{\text{.... mg of the product per kg body weight and day} \times \text{Average body weight (kg)}}{\text{Average daily water intake (l/animal)}} = \text{....mg of the product per litre of drinking water}$$

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

## 10. WITHDRAWAL PERIOD

Meat and offal: pigs: 5 days

## 11. SPECIAL STORAGE PRECAUTIONS

Shelf life after first opening the immediate packaging: 3 months

Shelf life after dilution or reconstitution according to directions: 24 hours

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Store in the original container

Do not refrigerate or freeze.

## 12. SPECIAL WARNING(S)

### Special warnings (for each target species)

The uptake of medication by animals can be altered as a consequence of illness. For animals with a reduced water intake, treat parenterally using an appropriate injectable product.

Long term or repeated use should be avoided by improving management practice and thorough cleansing and disinfection.

### **Special precautions for use in animals**

Due to the likely variability (time, geographical) in the occurrence of resistance of bacteria for tiamulin, the use of the product should be based on bacteriological sampling and susceptibility testing and take into account official and local antimicrobial policies. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to tiamulin and may decrease the effectiveness of treatment with other pleuromutilins due to the potential for cross-resistance.

Strategic treatment should be limited to animals where tiamulin susceptible agents have been isolated in the herd.

### **Special precautions for the person administering the veterinary medicinal product to animals**

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. People with known hypersensitivity to tiamulin should avoid contact with the veterinary medicinal product.

### **Use during pregnancy, lactation or lay**

The product can be used during pregnancy and lactation.

### **Interaction with other medicinal products and other forms of interaction**

Tiamulin is known to produce clinically important – often lethal – interactions with ionophore antibiotics, including monensin, narasin and salinomycin. . Therefore, pigs should not receive products containing such compounds during or for at least 7 days before and 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..

### **Overdose (symptoms, emergency procedures, antidotes), if necessary**

A single oral dose of 100 mg/kg BW caused hyperpnoea and abdominal complaints in pigs. At a dose of 150 mg/kg the only effects on the central nerve system was lethargy. A dose of 55 mg/kg during 14 days caused increased salivation and a mild irritation of the stomach. Tiamulin hydrogen fumarate has a relatively high therapeutic index in pigs. The minimum lethal dose has not been established in pigs.

If suspected adverse reactions do occur due to overdose, the medication should be discontinued and appropriate symptomatic treatment should be initiated.

**Incompatibilities**

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal product.

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED****15. OTHER INFORMATION**

Block bottomed zipped 1 kg bag Polyethylene terephthalate/aluminium/low density Polyethylene

When the container is opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.