

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Block bottomed zipped 1 kg bag of polyethylene terephthalate/aluminium/low density Polyethylene / 1 kg – 5 kg – 20 kg}**

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

Vetmulin 450 mg/g granules for use in drinking water

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each gram contains:

**Active substance:**

364.2 mg tiamulin (equivalent to 450.0 mg tiamulin hydrogen fumarate)

**3. PACKAGE SIZE**

1 kg

**4. TARGET SPECIES**

Pigs, chickens, turkeys.

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

In drinking water use.

**7. WITHDRAWAL PERIODS**

Withdrawal periods:

Pigs

Meat and offal: 2 days (8.8 mg tiamulin hydrogen fumarate (equivalent to 19.6 mg of veterinary medicinal product)/kg body weight)

Meat and offal: 4 days (20 mg tiamulin hydrogen fumarate (equivalent to 44.4 mg of veterinary medicinal product)/kg body weight)

Chickens

Meat and offal: 2 days

Eggs: Zero days

Turkeys

Meat and offal: 6 days.

**8. EXPIRY DATE**

Exp: {mm/yyyy}>

Once opened use within 3 months.

Once diluted or reconstituted use within 24 hours  
Once opened, use by

**9. SPECIAL STORAGE PRECAUTIONS**

Store in the original container. Do not refrigerate or freeze.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

Huvepharma NV

**14. MARKETING AUTHORISATION NUMBER**

Vm 30282/4002

**15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

**PACKAGE LEAFLET**

**1. Name of the veterinary medicinal product**

Vetmulin 450 mg/g granules for use in drinking water for pigs, chickens and turkeys.

**2. Composition**

Each gram contains:

**Active substance:**

364.2 mg tiamulin (equivalent to 450.0 mg tiamulin hydrogen fumarate)

White to pale yellow granules.

**3. Target species**

Pigs, chickens and turkeys.

**4. Indications for use**

Pigs

Treatment of Swine Dysentery caused by *Brachyspira hyodysenteriae* susceptible to tiamulin. The presence of the disease in the herd must be established before the veterinary medicinal product is used.

Treatment of Porcine Colonic Spirochaetosis (colitis) caused by *Brachyspira pilosicoli* susceptible to tiamulin. The presence of the disease in the herd must be established before the veterinary medicinal product is used.

Treatment of Porcine Proliferative Enteropathy (ileitis) caused by *Lawsonia intracellularis* susceptible to tiamulin. The presence of the disease in the herd must be established before the veterinary medicinal product is used.

Treatment and metaphylaxis of Enzootic Pneumonia caused by *Mycoplasma hyopneumoniae*, including infections complicated by *Pasteurella multocida* susceptible to tiamulin.

Treatment of Pleuropneumonia caused by *Actinobacillus pleuropneumoniae* susceptible to tiamulin. The presence of the disease in the herd must be established before the veterinary medicinal product is used.

Chickens

Treatment and metaphylaxis of Chronic Respiratory Disease caused by *Mycoplasma gallisepticum* and Airsacculitis and Infectious Synovitis caused by *Mycoplasma synoviae* susceptible to tiamulin. The presence of the disease in the flock must be established before the veterinary medicinal product is used.

## Turkeys

Treatment and metaphylaxis of Infectious Sinusitis and Airsacculitis caused by *Mycoplasma gallisepticum*, *Mycoplasma synoviae* and *Mycoplasma meleagridis* susceptible to tiamulin. The presence of the disease in the herd or flock must be established before use.

## **5. Contraindications**

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not use in pigs and birds that could receive products containing ionophores such as monensin, narasin or salinomycin during or for at least seven days before or after treatment with tiamulin. Severe growth depression or death may result. See section 'Special warnings' for information regarding interaction between tiamulin and ionophores.

## **6. Special warnings**

### Special warnings:

Animals with reduced water intake and/or in a debilitated condition should be treated parenterally.

Water intake may be depressed during the administration of tiamulin in birds. It appears to be concentration-dependent with 500 mg tiamulin hydrogen fumarate (equivalent to 1.11 g of veterinary medicinal product) in 4 litres of water reducing intake by approximately 10% and 500 mg tiamulin hydrogen fumarate (equivalent to 1.11 g of veterinary medicinal product) in 2 litres of water by 15% in chickens. It does not appear to have any adverse effect on overall performance of the birds or efficacy of the veterinary medicinal product but water intake should be monitored at frequent intervals, especially in hot weather. In turkeys, it is more marked, with approximately 20% reduction and therefore it is recommended not to exceed a concentration of 500 mg tiamulin hydrogen fumarate in 2 litres of the drinking water.

Repeated use should be avoided by improving management practice and thorough cleansing and disinfection.

### Special precautions for safe use in the target species:

Use of the veterinary medicinal product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of target bacteria.

Inappropriate use of the veterinary medicinal product may increase the prevalence of bacteria resistant to tiamulin.

### Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Direct contact with the skin, eyes and mucous membranes and inhalation of dust should be avoided. Personal protective equipment consisting of overalls, impermeable rubber gloves, safety glasses and a disposable half-mask respirator conforming to European Standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143 should be worn when handling the veterinary medicinal product.

In case of accidental eye contact, rinse the eyes thoroughly with clean running water immediately. Seek medical advice if irritation persists and show the package leaflet or the label to the physician.

Contaminated clothing should be removed and any splashes on to the skin should be washed off immediately.

Wash hands after use.

Accidental ingestion should be avoided. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

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

#### Pregnancy and lactation:

Can be used in pigs during pregnancy and lactation.

#### Laying birds:

Can be used in laying chickens.

#### Fertility:

Can be used in breeding chickens and turkeys.

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

Tiamulin has been shown to interact with ionophores such as monensin, salinomycin and narasin and may result in signs indistinguishable from an ionophore toxicosis.

Animals should not receive products containing monensin, salinomycin or narasin during or at least 7 days before or after treatment with tiamulin. Severe growth depression, ataxia, paralysis or death may result.

If signs of an interaction do occur, stop both the administration of tiamulin-medicated drinking water and also the administration of ionophore-contaminated feed immediately. The feed should be removed and replaced with fresh feed not containing the anticoccidials monensin, salinomycin or narasin.

Concomitant use of tiamulin and the divalent ionophore anticoccidials lasalocid and semduramicin do not appear to cause any interaction, however the concomitant use of maduramicin may lead to a mild to moderate growth depression in chickens. The situation is transient and recovery normally occurs within 3-5 days following withdrawal of tiamulin treatment.

#### Overdose:

Chickens and turkeys:

Regarding poultry, there is a relatively high therapeutic index with tiamulin hydrogen fumarate and the likelihood of an overdose is considered remote especially as water intake and hence tiamulin hydrogen fumarate intake is reduced if abnormally high concentrations are given. The LD<sub>50</sub> is 1090 mg/kg body weight for chickens and 840 mg/kg body weight for turkeys. The clinical signs of toxicity in chickens are vocalisation, clonic cramps and lying in a lateral position. Signs in turkeys are: clonic cramps, lateral or dorsal lying position, salivation and ptosis.

Pigs:

Single oral doses of 100 mg tiamulin hydrogen fumarate/kg body weight in pigs caused hyperpnoea and abdominal discomfort. At 150 mg tiamulin hydrogen fumarate/kg body weight no central nervous system effects were noted except for tranquillisation. At 55 mg tiamulin hydrogen fumarate/kg body weight daily given for 14 days, a transient salivation and slight gastric irritation occurred. Tiamulin hydrogen

fumarate is considered to have an adequate therapeutic index in the pig and a minimum lethal dose has not been established. If signs of intoxication do occur promptly remove the medicated water and replace with fresh water.

Major incompatibilities:

Tiamulin is not compatible with ionophore antibiotics including monensin, narasin and salinomycin. See section 'Interaction with other medicinal products and other forms of interaction' of this package leaflet.

**7. Adverse events**

Pigs:

Very rare (<1 animal / 10.00000 animals treated, including isolated report(s)):	Erythema (skin rash)
	Skin oedema (swelling) <sup>1</sup>

<sup>1</sup> mild

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or using the contact details at the end of this leaflet, or via your national reporting system:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

**8. Dosage for each species, routes and method of administration**

In drinking water use.

When medicating large volumes of water, prepare a concentrated solution first and then dilute to the required final concentration.

Fresh solutions of tiamulin-medicated drinking water should be made up each day.

To ensure the correct dosage, body weight should be determined as accurately as possible to avoid underdosing. The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of tiamulin may need to be adjusted accordingly.

In order to avoid interactions between the ionophores and tiamulin, the veterinarian and farmer should check that the feed label does not state that it contains salinomycin, monensin and narasin.

The dosage of the veterinary medicinal product to be incorporated should be established according to the following formula:

$$\begin{array}{l} \text{Dose (mg veterinary} \\ \text{medicinal product} \\ \text{per kg body weight per} \\ \text{day} \end{array} \quad \times \quad \begin{array}{l} \text{Mean body weight (kg)} \\ \text{of animals to be treated} \end{array} = \dots \text{mg veterinary medicinal} \\ \text{product per liter of drinking} \\ \text{water}$$

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Mean daily water consumption (liter) per animal per day'

Chickens:

For the treatment and metaphylaxis of Chronic Respiratory Disease caused by *Mycoplasma gallisepticum* and Airsacculitis and Infectious Synovitis caused by *Mycoplasma synoviae*:

The dosage is 25 mg tiamulin hydrogen fumarate (equivalent to 55.6 mg of veterinary medicinal product)/kg body weight daily administered for the period of 3 to 5 consecutive days.

Turkeys:

For the treatment and metaphylaxis of Infectious Sinusitis and Airsacculitis caused by *Mycoplasma gallisepticum*, *Mycoplasma synoviae* and *Mycoplasma meleagridis*:

The dosage is 40 mg tiamulin hydrogen fumarate (equivalent to 88.9 mg of veterinary medicinal product)/kg body weight daily administered for the period of 3 to 5 consecutive days.

Pigs:

For the treatment of Swine Dysentery caused by *Brachyspira hyodysenteriae*:

The dosage is 8.8 mg tiamulin hydrogen fumarate (equivalent to 19.6 mg of veterinary medicinal product)/kg body weight daily administered in the drinking water of pigs for 3 to 5 consecutive days depending on the severity of the infection and/or the duration of the disease.

For the treatment of Porcine Colonic Spirochaetosis (colitis) caused by *Brachyspira pilosicoli*:

The dosage is 8.8 mg tiamulin hydrogen fumarate (equivalent to 19.6 mg of veterinary medicinal product)/kg body weight daily administered in the drinking water of pigs for 3 to 5 consecutive days depending on the severity of the infection and/or the duration of the disease.

For the treatment of Porcine Proliferative Enteropathy (ileitis) caused by *Lawsonia intracellularis*:

The dosage is 8.8 mg tiamulin hydrogen fumarate (equivalent to 19.6 mg of veterinary medicinal product)/kg body weight daily administered in the drinking water of pigs for 5 consecutive days.

For the treatment and metaphylaxis of Enzootic Pneumonia caused by *Mycoplasma hyopneumoniae*, including infections complicated by *Pasteurella multocida* susceptible to tiamulin.

The dosage is 20 mg tiamulin hydrogen fumarate (equivalent to 44.4 mg of veterinary medicinal product)/kg body weight daily administered for 5 consecutive days.

For the treatment of Pleuropneumonia caused by *Actinobacillus pleuropneumoniae* susceptible to tiamulin:

The dosage is 20 mg tiamulin hydrogen fumarate (equivalent to 44.4 mg of veterinary medicinal product)/kg body weight daily administered for 5 consecutive days.

## **9. Advice on correct administration**

The use of suitably calibrated weighing equipment is recommended.

The maximum solubility of the veterinary medicinal product is 10 gram/liter. In order to avoid interactions between the ionophores and tiamulin, the veterinarian and farmer should check that the feed label does not state that it contains salinomycin, monensin and narasin.

For chickens and turkeys, in order to avoid interactions between the incompatible ionophores monensin, narasin and salinomycin and tiamulin, the feed mill supplying the birds feed should be notified that tiamulin will be used and that these anticoccidials should not be included in the feed or contaminate the feed.

The feed should be tested for the ionophores prior to use if there is any suspicion that contamination of the feed might occur.

If an interaction does occur, stop tiamulin medication immediately and replace with fresh drinking water. Remove contaminated feed as soon as possible and replace with feed not containing the tiamulin-incompatible ionophores.

## **10. Withdrawal periods**

Pigs

Meat and offal: 2 days (8.8 mg tiamulin hydrogen fumarate (equivalent to 19.6 mg of veterinary medicinal product)/kg body weight)

Meat and offal: 4 days (20 mg tiamulin hydrogen fumarate (equivalent to 44.4 mg of veterinary medicinal product)/kg body weight)

Chickens

Meat and offal: 2 days

Eggs: Zero days

Turkeys

Meat and offal: 6 days

## **11. Special storage precautions**

Keep out of the sight and reach of children.

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.

When the bag is broached 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 bag should be discarded should be worked out. This discard date should be written in the space provided on the label.

Store in the original container.

Do not refrigerate or freeze.

## **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

### **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

### **14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES**

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

### **15. PID link (Do not print heading)**

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

### **16. Contact details**

Marketing authorisation holder and contact details to report suspected adverse reactions:

Huvepharma NV  
Uitbreidingstraat 80  
2600 Antwerpen  
Belgium  
+32 3 288 18 49  
pharmacovigilance@huvepharma.com

Manufacturer responsible for batch release

Biovet JSC  
39 Petar Rakov Str  
4550 Peshtera  
Bulgaria

### **17. Other information**

POM-V

Tiamulin hydrogen fumarate is persistent in soils.

Revised: May 2025  
AN: 02196/2024 & 02199/2024

Approved 20 May 2025

*Gavin Hall*