# PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Bottle of 1L; can of 5L}

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETMULIN 125 mg/ml Solution for use in drinking water for pigs and chickens

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: Active substance: Tiamulin hydrogen fumarate 125 mg (equivalent to tiamulin 101.2 mg)

#### 3. PACKAGE SIZE

1 L 5 L

## 4. TARGET SPECIES

Pigs and chickens (layer hens).

#### 5. INDICATIONS

# 6. ROUTES OF ADMINISTRATION

In drinking water use.

#### 7. WITHDRAWAL PERIODS

Pigs

Meat and offal: 2 days (8.8 mg tiamulin hydrogen fumarate/ kg body weight equivalent to 7 ml of veterinary medicinal product/100 kg body weight)

Meat and offal: 4 days (20 mg tiamulin hydrogen fumarate/ kg body weight, equivalent to 16 ml veterinary medicinal product)/100 kg body weight)

Chickens (laying hens):

Meat and offal: 2 days

Eggs: Zero days

# 8. EXPIRY DATE

Exp. {mm/yyyy} Shelf-life after first opening the immediate packaging: 3 months. Shelf life after dilution in drinking water: 24 hours. Once opened, use by: ....

## 9. SPECIAL STORAGE PRECAUTIONS

Store in the original container in order to protect from light.

## 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 NUMBERS**

Vm 30282/5021

#### **15. BATCH NUMBER**

Lot {number}

# PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

## PACKAGE LEAFLET

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

VETMULIN 125 mg/ml Solution for use in drinking water for pigs and chickens

# 2. Composition

Each ml contains:

#### Active substance:

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

## Excipients:

Methyl parahydroxybenzoate (E218)	0.90 mg
Propyl parahydroxybenzoate	0.10 mg

Clear, colourless to slightly yellow liquid.

# 3. Target species

Pigs and chickens (layer hens).

#### 4. Indications for use

The presence of the disease in the herd must be established before the veterinary medicinal product is used.

#### <u>In pigs</u>

For the treatment of Swine Dysentery caused by tiamulin susceptible *Brachyspira hyodysenteriae*.

For the treatment of Porcine Colonic Spirochaetosis (spirochaetal diarrhoea or colitis) caused by tiamulin susceptible *Brachyspira pilosicoli*.

For the treatment of Porcine Proliferative Enteropathy (ileitis) caused by tiamulin susceptible *Lawsonia intracellularis*.

For the treatment and methapylaxis of Enzootic pneumonia caused by tiamulinsusceptible *Mycoplasma hyopneumoniae*, including infections complicated by tiamulinsusceptible *Pasteurella multocida*.

#### In chickens (layer hens)

For the treatment and methaphylaxis of Chronic Respiratory Disease caused by tiamulinsusceptible *Mycoplasma gallisepticum* and Airsacculitis and Infectious Synovitis caused by tiamulin-susceptible *Mycoplasma synoviae*.

# 5. Contraindications

Do not use in animals that could receive products containing monensin, narasin or salinomycin during or for at least seven days before or after treatment with tiamulin. Severe growth depression or death may result.

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

See section 6 for information regarding interaction between tiamulin and ionophores.

## 6. Special warnings

Special warnings:

Water intake may be depressed during the administration of tiamulin in birds. Water intake should be monitored at frequent intervals, especially in hot weather.

Pigs with reduced water intake and/or in a debilitated (weak) condition should be treated parenterally (intravenously or intramuscularly).

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.

Use of the veterinary medicinal product deviating from the instructions of the package leaflet may increase the prevalence of bacteria resistant to tiamulin.

# <u>Special precautions to be taken by the person administering the veterinary medicinal</u> product to animals:

People with known hypersensitivity to tiamulin or parabens should administer the veterinary medicinal product with caution.

Both the veterinary medicinal product and the diluted veterinary medicinal product in drinking water may cause hypersensitivity reactions due to contact. Avoid contact of both the veterinary medicinal product and medicated water with the skin. Do not smoke, eat or drink when handling the veterinary medicinal product. Wear protective clothes and gloves when mixing and handling the veterinary medicinal product, and wash hands after use. In case of accidental contact with skin, rinse with plenty of clean water. Contaminated clothing should be removed.

Ingestion of the veterinary medicinal product or medicated water should be avoided. In the event of accidental ingestion, rinse, mouth with plenty of water.

In case of accidental ingestion or spillage onto skin, seek medical advice immediately and show the package leaflet or the label to the physician.

<u>Special precautions for the protection of the environment:</u> Tiamulin only degrades slowly in soils and may accumulate over years.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

## Laying birds:

Can be used in chickens (layer hens).

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

Severe growth depression, ataxia, paralysis (lameness) or death may result from the interaction of tiamulin with ionophores such as monensin, salinomycin and narasin. Animals should not receive products containing monensin, salinomycin or narasin during or at least 7 days before or after treatment with tiamulin. If signs of an interaction do occur, stop both the administration of tiamulin-medicated drinking water and 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. Simultaneous use of tiamulin and lasalocid or semduramicin do not appear to cause any interaction. Simultaneous use of maduramicin and tiamulin 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:

In pigs, single oral doses of 100 mg tiamulin hydrogen fumarate/kg body weight caused hyperpnoea and abdominal discomfort. At a dose of 150 mg tiamulin hydrogen fumarate/kg body weight, the only effect on the central nervous system was sedation. A dose of 55 mg tiamulin hydrogen fumarate/kg body weight during 14 days caused a transient salivation and a mild irritation of the stomach. Tiamulin hydrogen fumarate has an adequate therapeutic index in the pig (meaning that the dose that has a therapeutic effect is much lower than the dose causing toxicity), and therefore a minimum lethal dose for pigs has not been established.

The  $LD_{50}$  (the dose at which 50% of a tested chicken population died after a specified test duration) in chickens, is 1090 mg/kg body weight. Tiamulin hydrogen fumarate has a relatively high therapeutic index in birds. The likelihood of an overdose is low as water intake and hence tiamulin hydrogen fumarate intake is reduced if abnormally high doses are given. The clinical signs of acute toxicity in chickens are: vocalisation, clonic cramps and lying in a lateral position.

If signs of poisoning occur, rapidly remove the medicated water and replace it with fresh unmedicated water. Appropriate symptomatic treatment should be initiated.

#### Major incompatibilities:

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

# 7. Adverse events

Pigs:

Very rare	Erythema, skin oedema
(<1 animal / 10.000 animals treated, including isolated report(s)):	

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

e-mail: adverse.events@vmd.gov.uk

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

In drinking water use

<u>Pigs</u>

- For the treatment of Swine Dysentery caused by *Brachyspira hyodysenteriae*.

The dosage is 8.8 mg tiamulin hydrogen fumarate/kg body weight (equivalent to 7 ml of veterinary medicinal product/100 kg body weight) administered daily 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 /kg body weight (equivalent to 7 ml of veterinary medicinal product/100 kg body weight) administered daily 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 /kg body weight (equivalent to 7 ml of veterinary medicinal product/100 kg body weight) administered daily 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/kg body weight (equivalent to 16 ml of veterinary medicinal product/100 kg body weight) administered daily for 5 consecutive days.

# Chickens (layer hens)

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/kg body weight (equivalent to 20 ml of veterinary medicinal product/100 kg body weight) administered daily for the period of 3 to 5 consecutive days.

# 9. Advice on correct administration

# Administration:

To ensure a correct dosage, body weight should be determined as accurately as possible. The intake of medicated water depends on the actual body weight, the water consumption, the clinical condition of the animals, the environment and the age of the animal. In order to obtain the correct dosage, the concentration of tiamulin should be adjusted accordingly. Follow the instructions below to calculate the required daily amount of veterinary medicinal product:

ml veterinary medicinal product/ x	average body weight (kg)	=	ml veterinary medicinal product
kg body weight/ day	of animals to be treated		per litre of drinking water
average daily water inta	ke (l/animal)		. •

Use a sufficiently accurate device to obtain the required volume of veterinary medicinal product. Use clean containers for preparation of the medicated drinking water. Stir the medicated drinking water prepared with the veterinary medicinal product for at least 1 minute after preparation in order to assure homogeneity. When medicating large volumes of water, prepare a concentrated solution first and then dilute to the required final concentration. The maximum solubility of the veterinary medicinal product is 200 mL/ L

Medicated drinking water should be refreshed or replaced every 24 hours.

In order to avoid interactions between the ionophores and tiamulin, the veterinarian and farmer should check with the feed mill that the feed does not contain salinomycin, monensin and narasin.

For chickens, 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 have occurred.

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 salinomycin, monensin or narasin.

# 10. Withdrawal periods

Pigs:

Meat and offal: 2 days (8.8 mg tiamulin hydrogen fumarate/ kg body weight equivalent to 7 ml of veterinary medicinal product/100 kg body weight)

Meat and offal: 4 days (20 mg tiamulin hydrogen fumarate/ kg body weight, equivalent to 16 ml veterinary medicinal product/100 kg body weight)

## Chickens (layer hens):

Meat and offal: 2 days

Eggs: Zero days

# 11. Special storage precautions

Keep out of the sight and reach of children. Store in the original container in order to protect from light.

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. Shelf life of the veterinary medicinal product as packaged for sales: 3 years. Shelf life after first opening the immediate packaging: 3 months Shelf life after dilution in drinking water: 24 hours

# 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

Vm 30282/5021

The veterinary medicinal product is presented in 1 litre high density polyethylene (HDPE) bottles closed with polypropylene (PP) screw cap and low density polyethylene (LDPE) seal disc and 5 litre high density polyethylene (HDPE) jars, closed with HDPE ribbed cap with a tamper-evident ring.

Not all pack sizes may be marketed.

#### 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 <u>www.gov.uk</u>.

#### 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

Gavín Hall

Approved: 24 January 2025