## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETMULIN 162 mg/ml Solution for Injection for pigs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

**Active substances**
Tiamulin 162 mg

**Excipients**

| **Qualitative composition of excipients and other constituents** | **Quantitative composition if that information is essential for proper administration of the veterinary medicinal product** |
|---|---|
| Butyl parahydroxybenzoate | 0.324 mg |
| Propyl gallate (E310) | 0.163 mg |
| Ethanol (96%) | |
| Sesame oil, refined | |

Pale yellow oily solution

## 3. CLINICAL INFORMATION

### 3.1 Target species

Pigs.

### 3.2 Indications for use for each target species

For treatment and metaphylaxis of swine dysentery caused by *Brachyspira hyodysenteriae*.

For the treatment of enzootic pneumonia caused by tiamulin-susceptible *Mycoplasma hyopneumoniae* and mycoplasmal arthritis caused by tiamulin-susceptible *Mycoplasma hyosynoviae.*

### 3.3 Contraindications

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

### 3.4 Special warnings

Inflammation/scarring may occur at the site of injection. For this reason, it is recommended that the veterinary medicinal product should be administered into the muscle of the neck.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:
Due to the likely variability (time, geographical) in the occurrence of resistance of bacteria for tiamulin, the use of the veterinary medicinal product should be based on bacteriological sampling and susceptibility testing taking into account official and local antimicrobial policies. Use of the veterinary medicinal 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. Long term or repeated use should be avoided by improving management practice and thorough cleansing and disinfection. In the absence of a satisfactory response to treatment, the diagnosis should be reconsidered.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to tiamulin should administer the veterinary medicinal product with caution. Care should be taken to avoid self-injection. Direct contact with the skin, eyes and mucous membranes should be avoided when handling the veterinary medicinal product.
In case of accidental eye contact, irrigate the eyes thoroughly with clean running water immediately. Seek medical advice immediately and show the package leaflet or the label to the physician if irritation persists.
In case of accidental spillage onto skin, wash immediately with running water in order to minimise absorption through the skin.

Wash hands after use.

This veterinary medicinal 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 self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

### 3.6 Adverse events

Pigs:

| | |
|---|---|
| Rare<br>(1 to 10 animals / 10,000 animals treated): | Hypersensitivity reaction[1] (dermatitis[2], erythema[3], pruritus[4]). |

[1] 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.
[2] Acute.
[3] Cutaneous.
[4] Intense.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation.

### 3.8 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, salinomycin. Therefore, pigs should not receive products containing such compounds during or for at least seven days before or after treatment with this veterinary medicinal 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.

### 3.9 Administration routes and dosage

Intramuscular use.

To ensure a correct dosage, body weight should be determined as accurately as possible.

For the treatment of clinical swine dysentery:
8.1 mg tiamulin base per kg bodyweight (equivalent to 1 ml per 20 kg bodyweight) 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 bodyweight (equivalent to 1.5 ml/20 kg bodyweight) 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.

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.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

A single oral dose of 100 mg tiamulin/kg bodyweight caused hyperpnoea and abdominal discomfort in pigs. At a dose of 150 mg tiamulin /kg the only effect on the central nervous system was lethargy. A dose of 55 mg tiamulin/kg for 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.

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

### 3.12 Withdrawal periods

Meat and offal: 21 days

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code: QJ01XQ01

### 4.2 Pharmacodynamics

Tiamulin hydrogen fumarate is a semi-synthetic derivative of the diterpene antibiotic pleuromutilin, produced by *Pleurotus mutilis* later renamed *Clitopilus scyphoides*.
Tiamulin is active against pathogenic mycoplasmas, against most Gram-positive organisms and anaerobes. Tiamulin is bacteriostatic at therapeutic concentrations and has been shown to act at the

ribosome level and the primary binding site is on the 50S subunit and possibly a secondary site where the 50S and 30S subunits join. It appears to inhibit microbial protein production by producing biochemical inactive initiation complexes, which prevent elongation of the polypeptide chain.

Research has shown that resistant bacterial mutants can be created through multi step resistance. Horizontal transferable resistance has also been described (e.g. *vga* genes & *cfr* gene). In practice, resistance in mycoplasmas has been reported rarely. Resistance against *B. hyodysenteriae* has been seen and can vary geographically.
If response to treatment of dysentery with the veterinary medicinal product is poor, then the possibility of resistance must be considered. Cross-resistance between tiamulin and tylosin tartrate has been reported: micro-organisms that are resistant for tiamulin, are also resistant for tylosin tartrate, but not vice versa. Transferable resistance mechanism (*cfr*) can cause cross-resistance to lincosamides, streptogramins (A) and phenicols (florfenicol).
Resistance in *Brachyspira hyodysenteriae* can be caused by a point mutation in the 23S rRNA gene and/or the ribosomal protein L3 gene.

### 4.3 Pharmacokinetics

Following a single intramuscular administration at a dose rate of approximately 14 mg tiamulin per kg bodyweight, mean maximum tiamulin concentration (approximately 350ng/ml) was reached after approximately 3 hours. The mean terminal half-life is approximately 12 hours.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

See also section 3.8

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

### 5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months
Shelf life after first opening the immediate packaging: 28 days. Discard any product remaining in the container at this time

### 5.3 Special precautions for storage

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

### 5.4 Nature and composition of immediate packaging

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.

### 5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

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 national collection systems applicable to the veterinary medicinal product concerned.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

## 7. MARKETING AUTHORISATION NUMBER(S)

VPA10782/008/001

## 8. DATE OF FIRST AUTHORISATION

30/10/2009

## 9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

01 September 2025

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).