PARTICULARS TO APPEAR ON THE OUTER PACKAGE {carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETMULIN 162 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

162 mg Tiamulin

3. PACKAGE SIZE

100 ml

4. TARGET SPECIES

Pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use

7. WITHDRAWAL PERIODS

Withdrawal period:

Meat and offal: 21 days.

8. EXPIRY DATE

EXP { mm/yyyy }

Once broached use within 28 days. Discard any product remaining in the container at this time.

Once opened, use by

9. SPECIAL STORAGE PRECAUTIONS

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

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

Accidental injection is dangerous.

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 30282/4013

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {100 ml vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETMULIN 162 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

162 mg Tiamulin

3. TARGET SPECIES

Pigs

4. ROUTES OF ADMINISTRATION

Intramuscular use. Accidental injection is dangerous.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:

Meat and offal: 21 days.

6. EXPIRY DATE

Exp. { mm/yyyy }>Once broached use within 28 days. Discard any product remaining in the container at this time.

Once opened, use by

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

VETMULIN 162 mg/ml Solution for Injection for pigs

2. 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	
Sesame oil, refined	

Pale yellow oily solution.

3. Target species

Pigs.

4. Indications for use

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*.

5. 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.

6. Special warnings

Special warnings:

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

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 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.

Pregnancy and lactation:

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, 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.

Overdose:

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.

Major incompatibilities:

See section 'Interaction with other medicinal products and other forms of interaction'.

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

7. Adverse events

Pigs:

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction[1] (dermatitis[2] (inflammation), erythema[3] (redness), pruritus[4] (itching))

[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 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 using the contact details at the end of this leaflet, or via your national reporting system at:

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

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 severity of disease it may be necessary to continue treatment by orally administered tiamulin until 2 days after signs of disease have subsided.

9. Advice on correct administration

For intramuscular use.

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.

10. Withdrawal periods

Meat and offal: 21 days.

11. Special storage precautions

Keep out of the sight and reach of children.

Shelf life after first opening the immediate packaging: 28 days. Discard any product remaining in the container at this time

Store below 25°C.

Do not refrigerate or freeze. Protect from light.

Do not use after the expiry date stated on the label.

12. Special precautions for disposal

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 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 30282/4013

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

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.

16. Contact details

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

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium
Tel: +32 3 318 36 54
pharmacovigilance@huvepharma.com

Manufacturer responsible for batch release:

Biovet JSC
39 Petar Rakov Str
4550 Peshtera
Bulgaria

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

17. Other information

POM-V

Gavin Hall

Approved 28 November 2025