

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE { low density polyethylene bag and three-ply paper secondary bag /1 kg – 5 kg – 20 kg}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmulin 100 mg/g granules

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:

Active substance:

81 mg tiamulin (equivalent to 100 mg tiamulin hydrogen fumarate)

3. PACKAGE SIZE

0.25 kg, 1 kg

4. TARGET SPECIES

Pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In-feed use
For use in individual pigs.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 7 days.

8. EXPIRY DATE

Exp: {mm/yyyy}
Once opened use within 3 months.
Shelf life after mixing into meal or pelleted feed: 24 hours.
Once opened, use by...

9. SPECIAL STORAGE PRECAUTIONS

Store below 25°C. Store in a dry place. Protect from direct sunlight.
Store in the original container.

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 30282/4016

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Vetmulin 100 mg/g granules for pigs

2. Composition

Each gram contains:

Active substance:

81 mg tiamulin (equivalent to 100 mg tiamulin hydrogen fumarate)A yellowish granular material.

3. Target species

Pigs.

4. Indications for use

For the treatment of swine dysentery caused by *Brachyspira hyodysenteriae*.

5. Contraindications

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

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

Severe growth depression or death may result.

6. Special warnings

Special warnings:

The uptake of medication by animals can be altered as a consequence of illness. For animals with a reduced feed intake, treat parentally using an appropriate injectable veterinary medicinal product. Long term or repeated use should be avoided by improving management practice and thorough cleansing and disinfection.

Special precautions for safe use in the target species:

Do not use the veterinary medicinal product in liquid feed.

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 and take 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.

If there is no response to treatment within 3 days, the diagnosis should be re-established.

Avoid interactions between tiamulin and the ionophore products monensin, narasin and salinomycin. Inform the feed supplier that tiamulin will be used to avoid incorporating the above listed products in the feed and to avoid contamination of the feed. In all cases of a suspected contamination, test the feed for the presence of these ionophores before feeding. If adverse effects occur due to an interaction, stop administration of the feed immediately. Remove the contaminated feed as soon as possible and replace with uncontaminated feed.

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

Direct contact with the skin, eyes, 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.

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

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

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.

Wash hands after use.

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

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/kg BW caused hyperpnoea and abdominal complaints in pigs. At a dose of 150 mg/kg the only effect 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.

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:

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction e.g. dermatitis (inflammation of the skin) ¹ , erythema (skin rash) and pruritus (itch) ² ³ .
	skin oedema (swelling) ^{3,4}

¹ Acute

² Intense

³ If these typical side effects occur, stop treatment immediately and clean animals and pens with water. Normally, affected animals recover quickly. Symptomatic treatment such as electrolyte therapy and an anti-inflammatory therapy may be useful.

⁴ 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 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

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

In-feed use.

For the treatment of swine dysentery caused by *Brachyspira hyodysenteriae*: the normal dose is 8.8 mg tiamulin hydrogen fumarate (equivalent to 7.1 mg tiamulin base) per kg bodyweight per day during 7-10 consecutive days. Considering a feed intake of 50 grams per kg BW, this dose can be achieved by mixing 1.75 g veterinary medicinal product into 1 kg of feed (175 ppm).

Examples of g of veterinary medicinal product per animal

BW of animal	Gram of veterinary medicinal product /animal
20	1.8
25	2.2
30	2.6
35	3.1
40	3.5
45	4.0
50	4.4
60	5.3
70	6.2
80	7.0
90	7.9
100	8.8
125	11.0
150	13.2

9. Advice on correct administration

The veterinary medicinal product should be administered to small quantities of feed for immediate consumption by individual animals. Pigs to be treated should be separated and treated individually. For treatment of larger groups, it is recommended to use tiamulin medicated premix for feeding stuff.

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

In case of an altered feed intake (weight class, age, environment) adjust the incorporation in order to guarantee an intake of 8.8 mg tiamulin hydrogen fumarate per kg per day.

In order to achieve a homogeneous intake it is recommended to use a premixture. The required amount of veterinary medicinal product can first be mixed with 10 % of the intended volume of feed. This premixture should then further be mixed homogeneously with the feed.

Alternatively the veterinary medicinal product can be mixed thoroughly into a part of the daily feed ratio and this can be administered prior to the feeding. It has to be ensured, that the calculated dose is completely taken up by the animals.

Consideration must be given to pigs whose daily feed intake is reduced or restricted. The required amount of veterinary medicinal product must be measured by a suitably calibrated weighing equipment.

The veterinary medicinal product should only be added to dry non-pelleted feed. If animals don't recover within 3 days after oral medication, diagnosis should be reconsidered and treatment should be changed, if necessary.

The treated feed must be prepared daily just before administration to the animals.

10. Withdrawal periods

Meat and offal: 7 days

11. Special storage precautions

Keep out of the sight and reach of children.

Store below 25 °C. Store in a dry place. Protect from direct sunlight. Store in the original container.

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

Shelf life after first opening the container: 3 months

Shelf life after mixing into meal or pelleted feed: 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 30282/4016

Pack size:

0.25 kg, 1kg, Low density polyethylene bag and three-ply paper secondary bag.

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 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

For animal treatment only.

Approved 17 June 2025

Gavin Hall