LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETMULIN 100 mg/g Oral Granules for pigs
Tiamulin hydrogen fumarate

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each gram contains: Tiamulin hydrogen fumarate 100 mg (equivalent to tiamulin 81 mg)

3. PHARMACEUTICAL FORM

Oral Granules.
A yellowish granular material

4. PACKAGE SIZE

0.25 kg, 1 kg,

5. TARGET SPECIES

Pigs.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In-feed use
For use in individual pigs. Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 7 days

9. SPECIAL WARNING(S), IF NECESSARY

For oral administration only after incorporation in feed.
Animals should not receive products containing monensin, salinomycin or narasin during or for at least seven days before or after treatment with the product.
Read package leaflet for full user safety warnings before use of this product

10. EXPIRY DATE

<EXP {month/year}>
Feed to which the oral granules has been added should be replaced if not consumed within 24 hours.

Once opened, use by …

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only – to be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

PACKAGE LEAFLET

VETMULIN 100 mg/g Oral Granules for pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder

Huvepharma NV, Uitbreidingstraat 80, 2600 Antwerpen, Belgium

Manufacturer **responsible for batch release**

Biovet JSC, 39 Petar Rakov Str, 4550 Peshtera - Bulgaria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETMULIN 100 mg/g Oral Granules for pigs
Tiamulin hydrogen fumarate

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Active substance:
Each g contains:
Tiamulin hydrogen fumarate 100 mg (equivalent to tiamulin 81 mg)
.
A yellowish granular material

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to the active ingredient 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 product.

6. ADVERSE REACTIONS

In rare cases, hypersensitivity to tiamulin following oral administration is reported in terms of acute dermatitis with cutaneous erythema and intense pruritus. On rare occasions erythema or mild oedema of the skin may occur in pigs following the use of tiamulin.The adverse reactions are usually mild and transient but in very rare cases may be serious. 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.

If you notice any serious effects not mentioned in this leaflet, please inform your veterinary surgeon
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7. TARGET SPECIES

Pig.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral administration only only after incorporation into feed.

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 product into 1 kg of feed (175 ppm).

Examples of g of product per animal

BW of animal	Gram of 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

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.

If animals don't recover within 3 days after oral medication, diagnosis should be reconsidered and treatment should be changed, if necessary

9. ADVICE ON CORRECT ADMINISTRATION

The 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 to avoid underdosing

In order to achieve a homogeneous intake it is recommended to use a premixture. The required amount of 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 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 product must be measured by a suitably calibrated weighing equipment

The product should only be added to dry non-pelleted feed

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

10. WITHDRAWAL PERIOD

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 after the expiry date stated on the label.
Shelf life after first opening the container: 3 months

12. SPECIAL WARNING(S)

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 product.

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 product. Severe growth depression or death may result.

Avoid interactions between tiamulin and the ionophore products monensin, narasin and salinomycin. Inform the feed supplier that tiamulin will be used to avoid the incorporation of the above listed products in the feed and to avoid contamination of the feed. In all cases of a suspected contamination, the feed should be tested on the presence of these ionophores first. If there is interaction, stop the administration of tiamulin immediately. Remove as soon as possible the contaminated feed and replace with feed that does not contain ionophores, which are not compatible with tiamulin.

Due to the likely variability (time, geographical) in the occurrence of resistance of bacteria for tiamulin,the useof the product should be based on susceptibility testing and take into the account official and local antimicrobial policies.

Use of the 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.

Tiamulin may lessen the antibacterial activity of beta-lactam antibiotics, whose action is dependent on bacterial growth.

The product can be used during pregnancy and lactation

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

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.

User warnings

Direct contact with the skin, eyes and mucous membranes should be avoided by wearing overalls, impermeable rubber gloves and safety glasses when mixing or handling the product.
In case of accidental eye contact, irrigate the eyes thoroughly with clean running water immediately. Seek medical advice if irritation persists.
When handling the product, inhalation of the dust must be avoided by wearing 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.
Accidental ingestion should be avoided.
Contaminated clothing should be removed and any splashes on to the skin should be washed off immediately.
Wash hands after use.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or label to the physician.
People with known hypersensitivity to tiamulin should avoid contact with the veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack size:

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

For animal treatment only.
To be supplied only on veterinary prescription.

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