LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETMULIN 162 mg/ml Solution for Injection for pigs.
Tiamulin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance

Tiamulin	162 mg/ml

Excipients

Butyl parahydroxybenzoate	0.324 mg/ml
Propyl gallate (E310)	0.163 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml.

5. TARGET SPECIES

Pigs.

6. INDICATION(S)

See package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 21 days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous – see package leaflet before use.

10. EXPIRY DATE

<EXP {month/year}>

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

11. SPECIAL STORAGE CONDITIONS

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

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium
Tel: +32 3 288 1849
Fax: + 32 3289 7845
E-mail: customerservice@huvepharma.com

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

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

LEAFLET

VETMULIN 162 mg/ml Solution for Injection for pigs
tiamulin

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

Marketing authorisation

Huvepharma NV, Uitbreidingstraat 80, 2600 Antwerpen, Belgium

Manufacturer

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETMULIN 162 mg/ml Solution for Injection for pigs.

tiamulin

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

Active substance
Tiamulin 162 mg/ml

Excipients
Butyl parahydroxybenzoate 0.324 mg/ml
Propyl gallate (E310) 0.163 mg/ml

Pale yellow oily solution

4. INDICATION(S)

For treatment and prevention, of swine dysentery caused by *Brachyspira hyodysenteriae*.
The product is not appropriate for use for the prevention of disease at the level of herd treatment but should only be used for prevention of swine dysentery in individual animals with a known history of exposure to diseased animals.

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

6. ADVERSE REACTIONS

In rare cases, hypersensitivity to tiamulin is reported in terms of acute dermatitis with cutaneous erythema and intense pruritus. The adverse reactions are 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.

7. TARGET SPECIES

Pigs.

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

Amount(s) to be administered and administration route

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing

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 PERIOD

Meat and offal: 21 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight 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 WARNING(S)

The product is not appropriate for use for the prevention of disease at the level of herd treatment but should only be used for prevention of swine dysentery in individual animals with a known history of exposure to diseased animals

Special precautions for use in animals

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.

Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies.

Inappropriate use of the product may increase the prevalence of bacteria resistant to tiamulin and may decrease the effectiveness of treatment with tiamulin related substances

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 for the person administering the veterinary medicinal product to animals

People with known hypersensitivity to tiamulin should handle the product carefully.
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 if irritation persists.
In case of skin contact, wash immediately with running water in order to minimise absorption through the skin.
Wash hands after use.

This 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 injection, seek medical advice immediately. Show the package leaflet or the label to the physician.

Use during pregnancy, lactation or lay

The product 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 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 (symptoms, emergency procedures, antidotes), if necessary

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

Incompatibilities

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

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

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14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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

OUTER CARTON

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Tiamulin

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3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml.

5. TARGET SPECIES

Pigs.

6. INDICATION(S)

See package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 21 days.

9. SPECIAL WARNING(S), IF NECESSARY

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10. EXPIRY DATE

<EXP {month/year}>

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11. SPECIAL STORAGE CONDITIONS

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16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

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