LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmulin 125 mg/ml Oral Solution for use in drinking water for pigs

Tiamulin hydrogen fumarate.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance

Tiamulin hydrogen fumarate 125 mg (equivalent to 101.2 mg tiamulin

Excipients

Methylparahydroxybenzoate (E218)
Propylparahydroxybenzoate

3. PHARMACEUTICAL FORM

Oral solution for use in drinking water. Clear colourless to slightly yellow liquid.

4. PACKAGE SIZE

1 litre
5 litres

5. TARGET SPECIES

Pigs

6. INDICATION(S)

See package leaflet

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In drinking water
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat & Offal: 5 days

9. SPECIAL WARNING(S), IF NECESSARY

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10. EXPIRY DATE

<EXP {month/year}>
Once opened, use within 3 months
Once diluted, use within 24 hours
Once opened use by:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25° C.

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

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

Manufacturer responsible for batch release in the EEA.

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

16. MARKETING AUTHORISATION NUMBER

Vm 30282/4014

17. MANUFACTURER'S BATCH NUMBER

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

PACKAGE LEAFLET

Vetmulin 125 mg/ml Oral Solution for use in drinking water for pigs

Tiamulin hydrogen fumarate

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 responsible for batch release

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmulin 125 mg/ml Oral solution for use in drinking water for pigs.

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

Each ml contains:

Active substance

Tiamulin hydrogen fumarate 125 mg (equivalent to 101.2 mg tiamulin

Clear colourless to slightly yellow liquid.

Excipients

Methyl parahydroxybenzoate (E218): 0.90 mg
Propyl parahydroxybenzoate: 0.10 mg

4. INDICATION(S)

In pigs

For the treatment of swine dysentery caused by or further complicated by tiamulin-susceptible *Brachyspira hyodysenteriae.*

For the treatment of enzootic pneumonia and the reduction of lesions caused by tiamulin-susceptible *Mycoplasma hyopneumoniae.*

The presence of the disease in the herd should be established before use

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to the active substance or to any of the excipient.

Do not use in the case of resistance to tiamulin.Do not administer products containing monensin, salinomycin, narasin, maduramicin or other ionophores 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 cutaneous and genital erythema and pruritus. The adverse reactions are often 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, the animals recover fast thereafter. Symptomatic treatment such as electrolyte therapy and an anti-inflammatory therapy may be useful. If you notice any serious or other effects not mentioned in this leaflet, please inform your veterinary surgeon

7. TARGET SPECIES

Pigs

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

Swine dysentery

8.8 mg tiamulin hydrogen fumarate per kg bodyweight per day (equivalent to 7ml product per 100 kg bodyweight per day) for 5 consecutive days.

Enzootic pneumonia

15-20 mg tiamulin hydrogen fumarate per kg bodyweight per day (equivalent to 12 – 16 ml product per 100 kg bodyweight per day) for 5 days.

Administration:

The uptake of medicated water depends on the actual body weight, the water consumption, the clinical condition of the animals, the environment, the age and the kind of feed provided. In order to obtain the correct dosage, the concentration of tiamulin should be calculated, as follows:

$$\frac{\text{.....ml Vetmulin 125 mg/ml oral solution for use in drinking water per kg body weight and day} \times \text{Average body weight (kg)}}{\text{Average daily water intake (l/animal)}} = \text{....ml Vetmulin 125 mg/ml oral solution for use in drinking water per litre of drinking water}$$

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing. The required doses should be measured by suitably calibrated measuring equipment.

Medicated water should be refreshed every 24 hours. The uptake of consistent amounts of drinking water should be ensured by sufficient drinking facilities.

To avoid formation of resistance by consumption of tiamulin in sub therapeutic doses, the watering equipment has to be cleaned adequately at the end of treatment.

9. ADVICE ON CORRECT ADMINISTRATION

The uptake of medication by animals can be altered as a consequence of illness.

In case of insufficient uptake of water, animals should be treated parenterally’

10. WITHDRAWAL PERIOD

Meat and offal
5 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25° C.
Shelf-life after dilution according to directions: 24 hours
Shelf-life after first opening the immediate packaging: 3 months
Do not use this veterinary medicinal product after the expiry date which is stated on the label after “EXP”. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

The uptake of medication by animals can be altered as a consequence of illness.

In case of insufficient uptake of water, animals should be treated parenterally.
Long term or repeated use should be avoided by improving management practice and thorough cleansing and disinfection.

Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies. (please delete paragraph of strategic treatment…)

Severe growth depression or death may result if animals receive products containing monensin, salinomycin, narasin, maduramicin or other ionophores during or for at least seven days before or after treatment with the product.

Use of the product deviating from the instructions given in the SPC may increase prevalence of bacteria resistant to tiamulin and may decrease the effectiveness of treatment with other pleuromutilins, macrolides and lincosamides due to potential resistance.

The product can be used during pregnancy and lactation.

Tiamulin may lessen the antibacterial activity of ß-lactam antibiotics whose action is dependant on bacterial growth

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

If signs of poisoning are observed, withdraw rapidly the medicated water and replace it with fresh water. Appropriate symptomatic treatment should be initiated

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

User safety warnings:

People with known hypersensitivity to the active substance must not administer the veterinary medicinal product

When mixing, direct contact with the skin and mucous membranes should be avoided. Accidental ingestion should be avoided. Wear overalls, safety glasses, mask and impervious gloves when handling or mixing the product. Contaminated clothing should be removed and any splashes on to the skin should be washed off immediately. If accidental eye contact occurs, immediately rinse thoroughly with water. Seek medical advice if irritation persists.

Wash hands after use.

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

Medicines should not be disposed of via wastewater or household waste. Ask your veterinarian how to dispose of medicines no longer required.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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

Vetmulin 125 mg/ml is presented in a 1 litre white high density polyethylene bottle with white polypropylene tamper-evident closure sealed with white foamed disk and in high density polyethylene can of 5 L, closed with high density polyethylene ribbed cap with a tamper-evident ring.

Approved 10 April 2017