PACKAGE LEAFLET

Vetmulin 100 g/kg premix for medicated feeding stuff 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

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 100 g/kg Premix for medicated feeding stuff for pigs

Tiamulin hydrogen fumarate

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

Each kg contains Tiamulin hydrogen fumarate 100 g (equivalent to tiamulin 82 g)

A yellowish free-flowing granular material.

4. INDICATION(S)

For treatment and prevention, when the disease is present at herd level, of swine dysentery caused by *Brachyspira hyodysenteriae* susceptible to tiamulin. The presence of disease in the herd should be established before use.

5. CONTRAINDICATIONS

Do not use in case of known hypersensitivity to the active substances or any of the excipients.

Do not use in case of resistance to tiamulin.

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 (see Special warnings).

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. 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 or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs

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

For oral administration only after incorporation in feed.

For the treatment and prevention, when disease is confirmed at the herd level, of swine dysentery:

8.8 mg tiamulin fumarate (equivalent to 7.1 mg tiamulin base) per kg bodyweight per day for 7-10 consecutive days. Assuming a feed intake of 50 g/kg BW, this dose is obtained by mixing 1.76 kg of product per tonne of feed (175 ppm). In case of an altered feed intake (weight class, age, environment), adjust the incorporation rate in order to guarantee an intake of 8.8 mg tiamulin fumarate (equivalent to 7.1 mg tiamulin base) per kg per day.

9. ADVICE ON CORRECT ADMINISTRATION

The uptake of medicated feed depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of tiamulin should be adjusted using the following formula:

$$\textit{Kg premix/tonne} = \frac{\textit{Dose rate (mg/kg) x mean bodyweight (kg)}}{\textit{Mean feed intake (kg) x premix strength (mg/g)}}$$

Medicated feed may be pelleted using a pre-conditioning step for 5 minutes at a temperature not exceeding 75°C.

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

Do not use the product in liquid feed.

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.

Shelf life after first opening the immediate packaging: 3 months
Shelf life after incorporation in the feed: 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. For animals with a reduced feed intake, treat parenterally using an appropriate injectable product.

Long term or repeated use should be avoided by improving management practice and thorough cleansing and disinfection.

Special precautions for use in animals

Do not use the product in liquid feed.

Due to the likely variability (time, geographical) in the occurrence of resistance of bacteria for tiamulin, the use of the product should be based on bacteriological sampling and susceptibility testing, taking into 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

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

Inform the feed supplier that tiamulin will be used, to avoid incorporating of ionophore products containing monensin, narasin and salinomycin products in the feed and to avoid contamination of the feed. In case 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 for the person administering the veterinary medicinal product to animals
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.
Contaminated clothing should be removed and any splashes on to the skin should be washed off immediately.
Wash hands after use.
Accidental ingestion should be avoided .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.

Use during pregnancy, lactation
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
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 effects 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.

Incompatibilities
In the absence of compatibility 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

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

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.
When the container is opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label

Presentations: 5 kg and a 20 kg polyethylene bag in an outer paper bag and in a 1 kg Polyethylene terephthalate/aluminium/low density polyethylenebag.

Not all pack sizes may be marketed.

Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.