LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmulin 100 g/kg Premix for medicated feeding stuff for pigs, chickens, turkeys and rabbits

tiamulin hydrogen fumarate

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each kg contains Tiamulin hydrogen fumarate 100 g (equivalent to tiamulin 81g)

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff.

4. PACKAGE SIZE

1kg, 5 kg and 20 kg

5. TARGET SPECIES

Pigs
Chickens (broiler, replacement pullet, layer/breeder)
Turkeys (poult (grower) and breeder)
Rabbits

6. INDICATION(S)

See package leaflet before use

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration only after incorporation in feed. Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Pigs
Meat and offal: 6 days.
Chickens
Meat and offal: 1 day.
Eggs: Zero days.
Turkeys

Meat and offal: 4 days.
Rabbits
Meat and offal: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Animals should not receive products containing monensin, salinomycin or narasin during or for at least seven days before or after treatment with the product.

10. EXPIRY DATE

<EXP {month/year}>
Shelf life after incorporation into meal or pelleted feed: 3 months.

Shelf life after first opening the immediate packaging: 3 months.

Once broached, 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

Dispose of waste material 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 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)

Vm 30282/4011

17. MANUFACTURER'S BATCH NUMBER

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

PACKAGE LEAFLET

Vetmulin 100 g/kg premix for medicated feeding stuff for pigs, chickens, turkeys and rabbits

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 g/kg Premix for medicated feeding stuff for pigs, chickens, turkeys and rabbits

Tiamulin hydrogen fumarate

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

Each kg contains Tiamulin hydrogen fumarate 100g (equivalent to tiamulin 81g)

A yellowish free-flowing granular material.

4. INDICATION(S)

Pigs
For the treatment and metaphylaxis, when the disease is present in the group, of swine dysentery caused by Brachyspira hyodysenteriae susceptible to tiamulin. The presence of the disease in the group must be established before use.
For the treatment of colitis caused by Brachyspira pilosicoli
For the treatment of ileitis caused by Lawsonia intracellularis
For the treatment of enzootic pneumonia caused by Mycoplasma hyopneumoniae
Chickens
For the treatment and metaphylaxis, when the disease is present at herd level, of chronic respiratory disease (CRD) and airsacculitis caused by Mycoplasma gallisepticum and Mycoplasma synoviae susceptible to tiamulin. The presence of the disease in the herd should be established before use.
Turkeys
For the treatment and metaphylaxis, when the disease is present at herd level, of infectious sinusitis and airsacculitis caused by Mycoplasma gallisepticum,

Mycoplasma meleagridis and Mycoplasma synoviae susceptible to tiamulin. The presence of the disease in the herd should be established before use.
Rabbits
For the treatment and metaphylaxis, when the disease is present at herd level, of epizootic rabbit enterocolitis (ERE) caused by pathogens susceptible to tiamulin. The presence of the disease in the herd should be established before use.

5. CONTRAINDICATIONS

Do not use in cases 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. Severe growth depression or death may result

6. ADVERSE REACTIONS

In rare cases, hypersensitivity to tiamulin following oral administration to pigs 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
Chickens (broiler, replacement pullet, layer/breeder)
Turkeys (poult (grower) and breeder)
Rabbits

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

For oral administration only after incorporation in medicated feed.

Pigs
Treatment and metaphylaxis of Swine Disentery caused B. hyodysenteriae, treatment of Porcine Colonic Spirochaetosis (colitis) caused by B. pilosicoli.

Dosage: 5 – 10 mg tiamulin hydrogen fumarate (equivalent to 4.05 – 8.1 mg tiamulin base) / kg bodyweight daily administered for 7 to 10 consecutive days. The dosage will normally be achieved by an inclusion level of 100 – 200 ppm tiamulin hydrogen fumarate in the finished feed providing that feed intake is unaffected.

Treatment of Porcine Proliferative Enteropathy (ileitis) caused by L. intracellularis
Dosage: 7.5 mg tiamulin hydrogen fumarate (equivalent to 6.075 mg tiamulin base) / kg bodyweight daily administered for 10-14 consecutive days. The dosage will normally be achieved by an inclusion level of 150 ppm tiamulin hydrogen fumarate in the finished feed providing that feed intake is unaffected.

Treatment of Enzootic Pneumonia caused by M. hyopneumoniae
Dosage: 5.0 – 10.0 mg tiamulin hydrogen fumarate (equivalent to 4.05 – 8.1 mg tiamulin base) / kg bodyweight daily administered for 7 to 10 consecutive days. The dosage will normally be achieved by an inclusion level of 100 - 200 ppm tiamulin hydrogen fumarate in the finished feed, providing that feed intake is unaffected.

Secondary infection by organisms such as Pasteurella multocida and Actinobacillus pleuropneumoniae may complicate enzootic pneumonia and require specific medication.

Chickens (broiler, replacement pullet, laying and breeding hens)
Treatment and metaphylaxis of chronic respiratory disease (CRD) caused by M. gallisepticum and airsacculitis and infectious synovitis caused by M. synoviae.
Dosage - Treatment and metaphylaxis: 25 mg tiamulin hydrogen fumarate (equivalent to 20.25 mg tiamulin base) / kg body weight daily administered for the period of 3 to 5 consecutive days. This is normally achieved by an inclusion level of 250 - 500 ppm tiamulin hydrogen fumarate in the finished feed provided that feed intake is unaffected.

Turkeys (young poults, breeding turkeys)
Treatment and metaphylaxis of infectious sinusitis and airsacculitis caused by M. gallisepticum, M. synoviae and M. meleagridis.
Dosage - Treatment and metaphylaxis: 40 mg tiamulin hydrogen fumarate (equivalent to 32.4 mg tiamulin base) / kg body weight daily administered for the period of 3 to 5 consecutive days. This is normally achieved by an inclusion level of 250 - 500 ppm tiamulin hydrogen fumarate in finished feed provided that feed intake is unaffected.

Metaphylaxis with tiamulin should only be initiated after confirmed infection with M. gallisepticum, M. synoviae and M. meleagridis and then as an aid in the metaphylaxis strategy to reduce the clinical signs and mortality from respiratory disease in flocks, where infection in ovum is likely because the disease is known to exist in the parent generation. The metaphylaxis strategy should include efforts to eliminate the infection from the parent generation.

Rabbits
Treatment of Epizootic Rabbit Enterocolitis (ERE) and metaphylaxis of ERE in farms with clinical signs of ERE in the previous fattening cycle as part of a programme including measures aiming to eradicate or control the infection in the farm.
Dosage: 3 mg tiamulin hydrogen fumarate (equivalent to 2.43 mg tiamulin base) / kg body weight daily. The dosage will normally be achieved by an inclusion level of 40 ppm tiamulin hydrogen fumarate in the finished feed provided that feed intake is unaffected. Treatment should be administered until 2 - 3 days after clinical signs

have resolved. Metaphylaxis should be administered during 3 – 4 weeks from the first week after weaning.

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:

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

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

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

10. WITHDRAWAL PERIODS

Pigs

Meat and offal: 6 days.

Chickens

Meat and offal: 1 day.

Eggs: Zero days.

Turkeys

Meat and offal: 4 days.

Rabbits

Meat and offal: Zero 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 container: 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)

Special warnings for each target species:

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.

In case of reduced feed intake, the inclusion levels in feed may need to be increased to achieve target dosage

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 susceptibility testing and take 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 crossresistance.

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 to be taken by 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
Can be used in pigs during pregnancy and lactation.
Can be used in laying and breeding chickens and turkeys.
Can be used in rabbits 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, animals should not receive products containing such compounds during or for at least seven days before or after treatment with this product. Severe growth depression, ataxia, paralysis or death may result.

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

Overdose

Pigs: A single oral dose of 100 mg/kg BW 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.

Chickens and turkeys: The LD_5 for chickens is 1290mg/kg and turkeys 840 mg/kg bodyweight. The clinical signs of acute toxicity in chickens are - vocalization, clonic cramps and lateral recumbency. In turkeys signs of acute toxicity include clonic cramps, lateral or dorsal recumbency, salivation and ptosis.
If signs of intoxication do occur promptly remove the medicated feed, replace with fresh unmedicated feed and apply supportive, symptomatic therapy.

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

February 2021

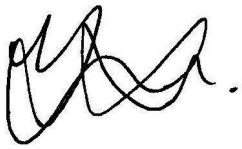
15. OTHER INFORMATION

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: polyethylene/paper bag of 5 kg and 20 kg and a polyethylene/aluminium/polyethylene terephatalate bag of 1 kg.

Not all pack sizes may be marketed.

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



Approved: 04 March 2021