RESPALIN 10 % PREMIX

Reg. No. 14/17.1.10/11

VETERINARY MEDICINE

SCHEDULING STATUS
S4

PROPRIETARY NAME AND DOSAGE FORM
Respalin 10 % Premix (powder).

COMPOSITION
Tiamulin hydrogen fumarate 100 g/kg
The excipients include; colloidal anhydrous silica and maize starch.

PHARMACOLOGICAL CLASSIFICATION
C 17.1.10 Antibacterial other

PHARMACOLOGICAL ACTION
Tiamulin hydrogen fumarate is a bacteriostatic semi-synthetic antibiotic which belongs to the pleuromutilin group of antibiotics. It acts at the ribosomal level to inhibit bacterial protein synthesis.

PHARMACODYNAMICS
Antimicrobial sensitivity to tiamulin:

Species	MIC* range µg/ml
Bacteroides vulgatus	0,25 – 1,0
Fusobacterium necrophorum	0,39
Pasteurelia multocida	1,9 – 31,2
Mycoplasma hyopneumonia	0,08 – 0,34
Mycoplasma hyosynoviae	0,03
Clostridium spp.	0,25
Mycoplasma gallisepticum	0,006 – 0,0125
Mycoplasma synoviae	0,006 – 0,39
Mycoplasma meleagrides	0,015 – 3,13
Staphyloccocus aureus	0,06 – 0,63
Clostridium perfringens	0,625 – 0,78

*Minimum inhibitory concentration.

Tiamulin has been shown to act at the 70S ribosome level. The primary binding site is on the 50S subunit and a possible secondary site is where the 50S and 30S subunits join. Tiamulin appears to inhibit microbial protein production by producing biochemically inactive initiation complexes, thus preventing elongation of the polypeptide chain. Bactericidal concentrations can be reached at approximately 50-100 times the bacteriostatic level.

PHARMACOKINETICS:
Chickens and turkeys:
Tiamulin absorption in chickens and turkeys is between 70 – 95 % after oral administration. Peak concentrations are reached within 2-4 hours. Tiamulin distributes widely throughout the body and has been shown to concentrate in the liver and kidneys which are the sites of excretion. Distribution in the lungs is up to 30 times the serum level. Between 55 and 65 % of the dose is excreted via bile and 15 to 30 % via the kidney. The metabolites are mainly microbiologically inactive. Excretion is quite rapid. Tiamulin-like activity can be detected in the serum at 24 hours and is below the detectable limits 36 hours after administration.

INDICATIONS
Chickens and turkeys:
RESPALIN 10 % PREMIX is indicated for the treatment of respiratory disease caused by *Mycoplasma gallisepticum* and infectious synovitis caused by *M.synoviae* in chickens and turkeys. It is also indicated for the prevention and control of respiratory disease caused by *Mycoplasma gallisepticum* in broilers as well as for the prevention and control of respiratory disease caused by *Mycoplasma gallisepticum* in breeding and laying hens.

CONTRA-INDICATIONS
Co-administration of RESPALIN 10 % PREMIX concomitantly with products containing monensin, narasin, salinomycin, or any other ionophores during, or for at least 7 days before or after treatment with RESPALIN 10 % PREMIX is contra- indicated. Severe growth depression or death may result.

WARNINGS AND WITHDRAWAL PERIOD IN THE CASE OF FOOD PRODUCING ANIMALS
Chickens: Meat and offal: 2 days. Eggs: 0 days.
Turkeys: 4 days.

RESPALIN 10 % PREMIX may not retain its activity three months after mixing with the animal feed. Discard any unused medicated feed if not used within 3 months of mixing. (See ***Dosage and directions for use***.)

SAFETY IN PREGNANCY AND LACTATION
RESPALIN 10 % PREMIX is suitable for use in laying and breeding chickens and turkeys.

DOSAGE AND DIRECTIONS FOR USE, INCLUDING PER AGE AND SPECIES DOSAGE
Treatment of respiratory disease caused by *Mycoplasma gallisepticum* and infectious synovitis caused by *M.synoviae* in chickens and turkeys:
RESPALIN 10 % PREMIX should be incorporated in the finished feed at 5 kg/ton of feed, to give 500 ppm of tiamulin hydrogen fumarate. This provides a dosage rate of approximately 25-50 mg tiamulin hydrogen fumarate/kg body weight/day. It should be fed as the sole ration for 3-5 days.

Prevention and control of respiratory disease caused by *Mycoplasma gallisepticum* in broilers:
RESPALIN 10 % PREMIX should be incorporated in the finished feed at 0,3 kg/ton of feed, to give 30 ppm of tiamulin hydrogen fumarate. This provides a dosage rate of approximately 3 mg tiamulin hydrogen fumarate/kg body weight/day. It should be fed as the sole ration for 1-5 weeks during the high risk period.

Prevention and control of respiratory disease caused by *Mycoplasma gallisepticum* in breeding and laying hens:
RESPALIN 10 % PREMIX should be incorporated in the finished feed at 0,5 kg/ton of feed, to give 50 ppm of tiamulin hydrogen fumarate. This provides a dosage rate of approximately 3 mg tiamulin hydrogen fumarate/kg/body weight/day. It should be fed as the sole ration for 1 week every month during the high-risk period.

Directions for mixing:
Thoroughly mix the required mass of Respalin 10 % Premix per metric ton of complete food to obtain the prescribed level of tiamulin activity. Respalin 10 % Premix should first be thoroughly mixed in a small quantity of complete food (20-30 kg) before it is incorporated into the remaining bulk of feed to be medicated.
Discard any unused medicated feed if not used within 3 months of mixing. (See ***Warnings***.)

SIDE EFFECTS AND SPECIAL PRECAUTIONS
Chickens and turkeys:
The following side effects have been observed; vocalisation, clonic cramps, lateral or dorsal recumbency, salivation and ptosis.

Special precautions for use in animals:
None.

Special precautions to be taken by the person administering RESPALIN 10 % PREMIX to animals:
Safety glasses, gloves and a face dust mask should be worn when mixing or handling the product in order to avoid direct contact with the mucous membrane or skin and avoid inhalation of dust. In case of accidental exposure, contaminated clothing should be removed and the affected area washed with soap and water. In case of accidental eye contact, the open eye should be copiously flushed with water. In case of accidental ingestion, seek medical advice immediately and show the package insert or label to the physician. People with known hypersensitivity to tiamulin hydrogen fumarate should administer the product with caution.

INTERACTIONS:
RESPALIN 10 % PREMIX interacts with products containing monensin, narasin, salinomycin or other ionophores. Animals should not receive RESPALIN 10 % PREMIX during or at least 7 days before or after treatment with these products. (see ***Contra-indications***). If signs of an interaction do occur, RESPALIN 10 % PREMIX medicated feed should be immediately stopped and replaced with fresh feed.

KNOWN SIGNS OF OVERDOSE AND PARTICULARS OF ITS TREATMENT
Chickens and turkeys:
The LD_{50} for chickens is 1290 mg/kg body weight and for turkeys, 840 mg/kg body weight. If signs of intoxication do occur, immediately remove the medicated feed and apply symptomatic, supportive therapy (see ***Side effects***).

IDENTIFICATION
White to off white coloured powder.

PRESENTATION
1 kg White woven PET (Polyethylene Terephthalate) sack (Height 333 - 340 mm, Width 245 - 255 mm) with transparent HMHDPE (High molecular High –Density polyethylene) liner. The sack is stitched sealed on three sides. Filled inner liner is heat sealed & sack is stitched at top side.

STORAGE INSTRUCTIONS
Store at or below 25 °C. Protect from light and moisture. For single-use only. Discard any unused portion. Keep out of reach of children and uninformed persons.

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KYRON

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