Package Inserts

I. Brand or Product Name:
FLUMICOL 20% W/V ORAL SOLUTION

II. Name and Strength of Active Substance(S):
Tilmicosin, 200 g in1000 ml

III. Product Description:
A brown yellow solution

IV. Target Species:
Chicken, Turkey

V. Pharmacodynamics:
Tilmicosin is a semi-synthetic antibiotic of the macrolide group and is believed to affect protein synthesis. It has bacteriostatic action but at high concentrations it may be bactericidal. This antibacterial activity is predominantly against Gram-positive microorganism with activity against certain gram-negative ones and Mycoplasma of a bovine,porcine,ovine and avian origin. In particular, its activity has been demonstrated against the following microorganism: Chickens and turkeys: Mycoplasma gallisepticum and Mycoplasma synoviae. Scientific evidence suggests that macrolides act synergistically with the host immune system. Macrolides appear to enhance phagocyte killing of bacteria. Cross-resistance between tilmicosin and other macrolides and lincomycin has been observed.

VI. Pharmacokinetics:
Whilst blood concentrations of tilmicosin are low, there is pH-dependent macrophage accumulation of tilmicosin in inflamed tissues. Poultry: As early as 6 hours after oral administration of 75mg tilmicosin/L drinking water, the average substance concentrations detected in lung and alveolar tissue were 0.63 µg/g and 0.30 µg/g respectively. 48 hours after the start of treatment, the tilmicosin concentrations in lung and alveolar tissue were 2.3 µg/g and 3.29 µg/g respectively. Turkeys: After oral administration of 75mg tilmicosin/L drinking water , the average substance concentrations detected in lung tissue, air sac tissue and plasma 5 days after the start of treatment were 1.89 µg/g , 3.71 µg/g and 0.02 µg/g respectively. The highest mean tilmicosin concentration detected for lung tissues was 2.19 µg/g at 6 days, for air sac tissue it was 4.18 µg/g at 2 days and in the plasma it was 0.172 µg/g at 3 days.

VII. Indication:
For the treatment of respiratory infections in chicken and turkey associated with Mycoplasma gallisepticum and Mycoplasma synoviae.

VIII. Recommended Dose and Administration:
Chickens and Turkeys (except hens producing eggs for human consumption): To be included in the drinking water at a daily dose of 15-20 mg/kg bodyweight in chickens and 10-27 mg/kg bodyweight in turkeys for 3 days, which may achieved by the inclusion of 75 mg tilmicosin per litre. (37.5 ml flumicol 20% per 100 liter) The uptake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of Flumicol 20% oral solution should be adjusted accordingly.

IX. Route of administration
Oral liquid

X. Contraindication:
Do not use in know cases of hypersensitivity to active ingredient.

XI. Warning and Precautions:
Must be diluted before administration to animals.

XII. Interaction with other medicinal product:
In the absent of compatibility studies, this veterinary medical product must not be mixed with other products.

XIII. Pregnancy and Lactation:
In the absense of toxicology study, this veterinary medicinal product must not be used during pregnancy and lactation. Do not use in laying birds producing eggs for human consumption.

XIV. Side Effects:
If suspected adverse reactions occur, treatment should be discontinued and to inform veterinarian/ local authority.

XV. Symptoms and Treatment of Overdose:
1. No symptoms of overdose have been seen in chickens given drinking water containing level of tilmicosin up to 375mg/litre (equivalent to 75-100mg/kg bodyweight or 5 times recommended dose) for 5 days; daily treatment with 75mg/litre (equivalent to maximum recorded dose) for 10 days resulted in faecal consistency.
2. No symptoms of overdose have been seen in turkeys given drinking water containing level of tilmicosin up to 375mg/litre (equivalent to 50-135mg/kg bodyweight or 5 times recommended dose) for 3 days; daily treatment with 75mg/litre(equivalent to maximum recorded dose) for 6 days also produced no symptoms of overdose.

XVI. Storage Condition:
Store below 30°C. Protect from heat and sunlight exposure.

XVII. Proposed Shelf Life:
After first opening of container: 30 days
After reconstitution or dilution: 1 day

XVIII. Withdrawal Period:
Chickens: 12 days Turkeys: 19 days Not authorized for use in laying birds producing eggs for human consumption. Do not use within 14 days of onset of the laying

XIX. Dosage Forms and packaging available:
In the form of liquid and packed in 1 L bottle.

XX. Name and Address of manufacturer/ marketing authorization holder:
NAM PHARMA SDN. BHD.
5, Lebuh Perusahaan klebang 11,
Taman Perindustrian Antarabangsa IGB,
31200 Chemor, Perak, Malaysia.

XXI. Date of Revision of Package Insert:
10/5/2012