

## Package Inserts

<p>I. Brand or Product Name: FLOD-LD 100MG/ML Oral Solution</p> <p>II. Name and Strength of Active Substance: Florfenicol, 100mg in 1ml</p> <p>III. Product Description: A light yellow colour, clear solution.</p> <p>IV. Target Species: Pigs</p> <p>V. Pharmacodynamics: Florfenicol is a broad-spectrum synthetic antibiotic in the phenicol group that is active against most Gram-positive and Gram-negative bacteria isolated from domestic animals. Florfenicol acts by inhibition of protein synthesis at the ribosomal level and is bacteriostatic. However, bactericidal activity has been demonstrated <i>in-vitro</i> against <i>Actinobacillus pleuropneumoniae</i> and <i>Pasteurella multocida</i> when florfenicol is present at concentrations above the MIC for up to 12 hours.</p> <p>VI. Pharmacokinetics: After absorption and distribution, florfenicol is extensively metabolised by pigs and rapidly eliminated, primarily in urine.</p> <p>VII. Indication: In pigs: Treatment and prevention at the group level where clinical signs are present of swine respiratory disease associated with <i>Actinobacillus pleuropneumoniae</i> and <i>Pasteurella multocida</i> susceptible to florfenicol. The presence of the disease should be established in the herd before initiating preventive treatment.</p> <p>VIII. Recommended Dose and Administration: To be administered in drinking water. 10 mg florfenicol per kg body weight daily (corresponding to 10 ml of the product / 100 kg b.w.) given for 5 consecutive days</p> <p>IX. Contraindication: Do not use in boars intended for breeding purposes. Do not use in case of hypersensitivity to the active substance or to the excipient.</p>	<p>X. Warning and Precautions: Special warning for each target species: The treated pigs should be placed under special observation. On each of the five days of treatment, unmedicated drinking water should not be given until the full daily amount of medicated drinking water has been ingested by pigs. If there are no signs of improvement after three days of treatment, the diagnosis should be reviewed and, if necessary, the treatment changed. Special precautions for use in animals: The veterinary medicinal product should be used in conjunction with susceptibility testing. Treatment should not exceed 5 days. Special precautions to be taken by the person administering the veterinary medicinal product to animals: People with known hypersensitivity to florfenicol or polyethylene glycols should avoid contact with the veterinary medicinal product. In case of accidental spillage onto skin rinse with water. In case of contact with eyes, rinse immediately with copious amounts of water. Personal protective goggles should be worn when handling the veterinary medicinal product. Other precautions: In order to prevent any adverse effects on algae and possible contamination of groundwater, manure from treated pigs must not be spread onto land without dilution with manure from untreated pigs. Manure from treated pigs must be diluted with at least 5 times the weight of manure from untreated pigs before it can be spread onto arable land.</p> <p>XI. Interaction with other medicinal product: No data available.</p> <p>XII. Pregnancy and Lactation: Studies in laboratory animals have not revealed any evidence of potential embryotoxic or foetotoxic effect of florfenicol. The safety of the veterinary medicinal product in sows has not been established during pregnancy and lactation. The use is not recommended during pregnancy and lactation.</p> <p>XIII. Side Effects: A slight reduction of water consumption by the animals, dark brown faeces and constipation may be observed during treatment. Commonly observed adverse effects are diarrhoea and/or peri-anal and rectal erythema/oedema which may affect approximately 40% of the animals. These effects are transient. In a few of the</p>	<p>affected animals, prolapse of the rectum, that resolves without treatment may be observed.</p> <p>XIV. Symptoms and Treatment of Overdose: In case of overdosing, a decrease in weight gain, food and water consumption, peri-anal erythema and oedema and modification of some haematological and biochemical parameters indicative of dehydration may be observed.</p> <p>XV. Withdrawal Period: Meat and offal is 20 days.</p> <p>XVI. Storage Condition: Stored at ≤ 30°C/ store below 30°C. Protect from direct sunlight.</p> <p>XVII. Proposed Shelf Life: As packaged for sale: 2 years After first opening of the immediate packaging: 28 days After dilution or reconstitution: 24 hours</p> <p>XVIII. Dosage Forms and packaging available: In liquid form, packed in 1L container.</p> <p>XIX. Name and Address of manufacturer NAM PHARMA SDN. BHD. 5, Lebuhr Perusahaan klebang 11, Taman Perindustrian Antarabangsa IGB, 31200 Chemor, Perak, Malaysia.</p> <p>XX. Name and Address Product holder KTY CHEMICALS SDN BHD 65, Jalan Cenderawasih 3, Taman Cenderawasih Indah, 14300 Nibong Tebal, SPS, Penang, Malaysia.</p> <p>XXI. Date of Revision of Package Insert: 04/04/2018</p>
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