Veterinary Package Insert

TP-Flor 200 SOL Florfenicol 200mg/ml Solution

PRODUCT DESCRIPTION
Light yellow to yellow colour liquid, which contains florfenicol 200mg in 1ml of solution (20% in w/v).

PHARMACODYNAMICS & PHARMACOKINETICS
Florfenicol is a synthetic broad spectrum antibiotic active against many gram-negative and gram-positive bacteria isolated from domestic animals. It acts by inhibiting bacterial protein synthesis. In vivo activity has been demonstrated against bacterial pathogens commonly associated with swine respiratory disease, including Actinobacillus pleuropneumoniae and Pasteurella multocida. In vitro activity has been demonstrated against Salmonella spp and Streptococcus suis and in vitro activity against Mycoplasma hyopneumoniae and Mycoplasma hyorrhinis has been detected. However, the clinical significance of this activity in swine is not known.

For Swine:

Florfenicol was detectable in the serum of all animals through 12 hours after gavage. After gavage of florfenicol on the fifth day, the maximum serum florfenicol concentrations were between 2.78 µg/mL and 7.34 µg/mL and the median terminal half life was 2.0 hours. The extent of bioavailability ranged from 24% to 97%.

For Chicken:

After the first oral gavage administration of florfenicol of 42 mg/kg bw/day for 3 days to broiler chicken, the highest concentration of florfenicol in serum (12200 µg/l) was measured after 30 minutes and then declined to reach 810 µg/l, 8 hours later. Florfenicol could not be detected in the serum, 60 hours after the last administration.

During a continuous treatment for broiler chicken with florfenicol in drinking water at a daily dose of 26 mg/kg bw for 18 hours for 3 days, the estimated mean serum concentration of florfenicol was 711 µg/l. No florfenicol was detected in the serum, 72 hours after the terminal dose.

INDICATION
Broiler Chickens: The product is indicated in broiler chickens for the treatment and control of air sacculitis associated with E. coli susceptible to florfenicol.

Swine: The product is indicated for the treatment of swine respiratory disease associated with Actinobacillus pleuropneumoniae and Pasteurella multocida.

RECOMMENDED DOSAGE AND ADMINISTRATION
Poultry (Broiler Chicken):

DOSAGE: 100 ppm (100 mg/L, i.e. 0.5ml of product in 999.5ml of drinking water) for 3 consecutive days in drinking water. This dosage rate is equivalent to 35 mg/kg body weight of birds.

ADMINISTRATION: The medicated water should be administered as the only source of drinking water for 3 consecutive days. Medication should be initiated promptly when disease attributed to E. coli is diagnosed. Prepare fresh stock solution and medicated water daily.

Note: If a positive clinical response is not noted within 48 hours of initiation of treatment, the diagnosis should be reevaluated.

Swine:

DOSAGE: 100 ppm (100 mg/L 0.5ml of product in 999.5ml of drinking water) for 5 consecutive days in drinking water.

This dosage rate is equivalent to 10 mg/kg body weight for pigs that are drinking 10% of their body weight.

ADMINISTRATION: The medicated water should be administered as the only source of drinking water for 5 consecutive days. Medication should be initiated promptly when swine respiratory disease is diagnosed. Prepare fresh stock solution and medicated water daily.

Note: If a positive clinical response is not noted within 48 hours of initiation of treatment, the diagnosis should be reevaluated.

CONTRAINDICATIONS
Do not use this product at any other proportioner setting. This will result in precipitation of product. This product is not recommended for use in automatic water proportioners if water hardness is greater than 275 ppm. Water proportioners should be tested for accuracy before use. Do not use or store this product in galvanized metal watering systems or containers. Do not operate chlorinators while administering medication.

WARNINGS & PRECAUTIONS.
Warning:

Not for human use - keep out of the reach of children. This product contains material that can be irritating to skin and eyes. Avoid direct contact with

skin, eyes and clothes. In case of accidental eye exposure, flush with water for 15 minutes. In case of accidental skin exposure, wash with soap and water. Remove contaminated clothing. Consult a physician if irritation persists.

Caution:

Swine:

Not for use in breeding swine. The effects of florfenicol on porcine reproductive performance, pregnancy and lactation have not been assessed.

Broilers (Chicken):

Not for animals from which eggs are produced for human consumption.

INTERACTIONS WITH OTHER MEDICATIONS
Data not available.

PREGNANCY AND LACTATION
Broiler Chickens: Do not feed to birds intended for breeding purposes. The effects of the product on the reproductive function of treated chickens have not been determined.

Swine: Not for use in breeding swine. The effects of florfenicol on porcine reproductive performance, pregnancy and lactation have not been assessed.

Hence, the use is not recommended during pregnancy and lactation.

ADVERSE EFFECTS
In swine, perianal inflammation may be observed in approximately 40% of the treated pigs. Rectal eversion may occur in about 6% of the treated pigs. These effects should resolve completely within one week. Transient diarrhea may occur with the use of this drug.

OVERDOSE & TREATMENT
The following effects have been selected on the basis of their potential clinical significance (possible signs in parentheses where appropriate)—not necessarily inclusive:

Pigs: with oral administration in the drinking water at a concentration of 1200 to 2000 mg per gallon (3 to 5 times the labeled dose) for 15 to 16 days (3 times the labeled duration) or with 4000 mg/gal (10 times the labeled dose) for 5 to 6 days:

Constipation, transient; decreased feed consumption

Poultry: No data available.

There is no specific treatment for florfenicol overdose. Therapy should be supportive.

WITHDRAWAL PERIOD
5 days for broiler chickens.

21 days for swine.

MAXIMUM RESIDUAL LIMIT (MRL)

Substance	Food	Maximum Residue Limits (MRLs) in µg/kg
Florfenicol	Chicken, muscle	100
	Chicken, skin & fat	200
	Chicken, liver	2500
	Chicken, kidney	750
	Pig, muscle	300
	Pig, skin & fat	500
	Pig, liver	2000
	Pig, kidney	500

Not for animal from which eggs are produced for human consumption.

STORAGE CONDITION
Store in a dry, cool place and avoid direct sunlight. It should be store at room temperature (30°C or below.)

SHELF LIFE
2 years.

After 1st opening, reconstitution or dilution, use within 24 hours.

PACKING
1 L

THYE PHARMA SDN. BHD.
(manufacturer & product registration holder)
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