

FLORCON- florfenicol solution, concentrate
Med-Pharmex, Inc.

FLORCON (FLORFENICOL)

FLORCON

(FLORFENICOL) An Antimicrobial

2.3% Concentrate Solution

For Oral Use in Swine Drinking Water Only.

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

ANADA #200-589, Approved by FDA.

For use in Animals Only

IMPORTANT: See Product Information sheet for complete directions and warnings before using.

Med-Pharmex, Incorporated
POMONA, CA 91767

Rev. Date: 11/16

DESCRIPTION: Florfenicol (Oral Concentrate) is a synthetic broad-spectrum antibiotic. Each milliliter (mL) of **FLORCON** 2.3% Concentrate Solution contains 23 mg florfenicol.

INDICATIONS: **FLORCON** 2.3% Concentrate Solution is indicated for the treatment of swine respiratory disease associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Salmonella choleraesuis*, and *Streptococcus suis* in swine.



DOSAGE AND ADMINISTRATION:

For Proportioner: To produce drinking water with a final concentration of 400 mg/gallon (100 ppm): Fill the bottle of **FLORCON** 2.3% Concentrate Solution with water to the fill line. Add the contents of the bottle to the mixing tank. Mix thoroughly. Confirm that the proportioner is set to deliver 1:128 (0.8%). Turn on the proportioner. Verify that the drinkers are operational.

For Bulk Tank: To produce drinking water with a final concentration of 400 mg/gallon (100 ppm): Add the **FLORCON** 2.3% Concentrate Solution to the drinking water in the bulk tank. Use one bottle of **FLORCON** 2.3% Concentrate Solution for every 128 gallons of water.

The medicated water should be administered as the only source of drinking water for five (5) consecutive days. Medication should be initiated promptly when swine respiratory disease is diagnosed.

PRECAUTIONS: 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.

 **RESIDUE WARNINGS:** Swine intended for human consumption must not be slaughtered within 16 days of the last treatment. Use of this product in a manner other than indicated or with dosages in excess of those included on this label may result in illegal drug residues in edible tissues. 

WARNINGS: NOT FOR HUMAN USE. KEEP OUT OF 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. The Safety Data Sheet (SDS) contains more detailed occupational safety information.

For customer service and/or a copy of the SDS, call 1-800-587-4306.

For adverse effects reporting, call 1-800-587-4306.

PRECAUTION: The effects of **FLORCON** 2.3% Concentrate Solution on swine reproductive performance, pregnancy, and lactation have not been determined. Do not use in swine intended for breeding.

ADVERSE REACTION: Perianal inflammation may occur transiently following treatment.

CLINICAL PHARMACOLOGY: Florfenicol is a bacteriostatic agent whose antimicrobial activity is linked to time above MIC.

The pharmacokinetic disposition of **FLORCON** 2.3% Concentrate Solution was evaluated in swine following oral gavage dosing (15 mg/kg), intravenous (IV) dosing (15 mg/kg), and during a five (5) day course of *ad libitum* administration in drinking water (100 ppm) (Table 1). Despite the rapid elimination seen after IV injection or oral gavage dosing, when administered in medicated drinking water, florfenicol concentrations in the serum of most swine were maintained well above 1.0 mcg/mL for the majority of the (5) day dosing interval. These results are consistent with product effectiveness when administered in drinking water concentrations of 100 ppm over a five (5) day dosing period.

Although the extent of oral drug absorption (F) tended to be variable (24% to 97% following a single oral gavage dose), florfenicol was rapidly absorbed. Its terminal elimination half-life ($T_{1/2}$) was also rapid, ranging between two (2) to three (3) hours.

The average systemic clearance (CL_B) following IV administration was 5.6 mL/kg/min. Since the florfenicol steady state volume of distribution (VD_{SS}) closely approximates that of total body water, peripheral tissue concentrations are expected to be similar to those concentrations observed in serum.

Table 1. Pharmacokinetic Parameter Values of Florfenicol following IV or Gavage Dosing

Parameter	Mean Value (% CV)
Vd_{SS}^a (L/kg)	0.95 (6)
CL_B^a (mL/kg/min)	5.57 (11)
$T_{1/2}^a$ (hrs)	2.2 (14)
F^b (%)	24-97
^a parameter estimate based on intravenous data	
^b parameter range based upon a single oral gavage dose	

MICROBIOLOGY: 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* and *in vitro* activity has been demonstrated against commonly isolated pathogens involved in swine respiratory disease including *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Salmonella choleraesuis*, and *Streptococcus suis*.

The minimum inhibitory concentration (MIC) of florfenicol was determined for isolates obtained from natural respiratory infections of swine from 1990-2001 (Table 2). Susceptibility testing followed the methods of the National Committee of Clinical Laboratory Standards. Reference strains included *Escherichia coli* ATCC 25922 with a QC range of 2-8 mcg/mL and *Actinobacillus pleuropneumoniae* ATCC 27090 with a QC range of 0.25-1 mcg/mL.

Table 2. MIC Values of Florfenicol Against Bacterial Isolates from Swine			
Organism	Isolate Numbers	MIC₉₀ * (mcg/mL)	MIC Range (mcg/mL)
<i>Actinobacillus pleuropneumoniae</i>	360	0.50	≤0.125-2.0
<i>Pasteurella multocida</i>	335	0.50	≤0.125-2.0
<i>Salmonella choleraesuis</i>	46	4.0	2.0-4.0
<i>Streptococcus suis</i>	203	2.0	0.5-2.0

*The minimum inhibitory concentration for 90 % of the isolates

ANIMAL SAFETY: A target animal safety study was conducted to evaluate the tolerance and effects of florfenicol when orally administered to swine via the drinking water at a rate of 400, 1200, and 2000 mg/gal (1x, 3x, or 5x the clinical dose) for fifteen (15) to sixteen (16) consecutive days (3x the clinical duration), and at 4000 mg/gal (10x clinical dose) for five (5) to six (6) consecutive days (1x the clinical duration).

Transient treatment-related constipation and anal swelling were seen in the 3x, 5x, and 10x treatment groups. The constipation in these groups was attributed in part to decreased water consumption during the medication period. There was a decrease in weight gains for the 3x, 5x, and 10x treatment groups compared with the nonmedicated control group. Transient treatment-related decreases in feed consumption were seen in the 3x, 5x, and 10x treatment groups compared with the nonmedicated control group. Transient treatment-related decreases in water consumption were noted in all test article-treated groups (1x, 3x, 5x, and 10x) compared with the nonmedicated control group.

The results show that **FLORCON 2.3% Concentrate Solution** can be safely administered to swine according to the recommended clinical regimen of 400 mg/gal in the drinking water for five (5) consecutive days.

STORAGE CONDITIONS: Store between 2°-25°C (36°-77°F).

HOW SUPPLIED: **FLORCON 2.3% Concentrate Solution** is supplied in one gallon plastic bottles with 2.2 liter fill.

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Rev. Date 11/16

For Use in
Animals Only

2.2 Liters

NDC 54925-090-22

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2.3% Concentrate Solution

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ANADA #200-589, Approved by FDA



Lot No./Exp. Date

FLORCON

florfenicol solution, concentrate

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:54925-090
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FLORFENICOL (UNII: 9J97307Y1H) (FLORFENICOL - UNII:9J97307Y1H)	FLORFENICOL	23 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54925-090-22	2200 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200589	02/07/2017	

Labeler - Med-Pharmex, Inc. (025353699)

Registrant - Med-Pharmex, Inc. (025353699)

Establishment

Name	Address	ID/FEI	Business Operations
Med-Pharmex, Inc.		025353699	manufacture

Revised: 3/2017

Med-Pharmex, Inc.