



Injectable Solution, An Antimicrobial 300 mg/mL

For Subcutaneous Use in Beef and Non-Lactating Dairy Cattle Only

Not for Use in Female Dairy Cattle 20 Months of Age or Older or in Calves to be Processed for Veal

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

DESCRIPTION: NUFLOOR GOLD® is an injectable solution of the synthetic antibiotic florfenicol. Each milliliter of sterile NUFLOOR GOLD® contains 300 mg of florfenicol, 300 mg of 2-pyrrolidone, and triacetin qs.

INDICATION: NUFLOOR GOLD® is indicated for treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis* in beef and non-lactating dairy cattle.

DOSAGE AND ADMINISTRATION: NUFLOOR GOLD® should be administered by a single subcutaneous injection at a dose rate of 40 mg florfenicol/kg body weight (6 mL/100 lb). Do not administer more than 15 mL at each site. The injection should be given only in the neck. Injection sites other than the neck have not been evaluated.

NUFLOR GOLD® Dosage Guide

ANIMAL WEIGHT (lb)	DOSAGE (mL)
100	6.0
200	12.0
300	18.0
400	24.0
500	30.0
600	36.0
700	42.0
800	48.0
900	54.0
1000	60.0

Recommended Injection Location:



CONTRAINDICATIONS: Do not use in animals that have shown hypersensitivity to florfenicol.

WARNINGS: NOT FOR HUMAN USE. KEEP OUT OF REACH OF CHILDREN. This product contains materials that can be irritating to skin and eyes. Avoid direct contact with skin, eyes, and clothing. 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. Accidental injection of this product may cause local irritation. Consult a physician immediately. The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information.

For customer service, to report suspected adverse reactions, or to obtain a copy of the MSDS, call 1-800-211-3573.

PRECAUTIONS: Not for use in animals intended for breeding purposes. The effects of florfenicol on bovine reproductive performance, pregnancy, and lactation have not been determined. Toxicity studies in dogs, rats, and mice have associated the use of florfenicol with testicular degeneration and atrophy.

Subcutaneous injection in cattle can cause a transient local tissue reaction that may result in trim loss of edible tissue at slaughter.

RESIDUE WARNINGS: Animals intended for human consumption must not be slaughtered within 44 days of treatment. Do not use in female dairy cattle 20 months of age or older. Use of florfenicol in this class of cattle may cause milk residues. A withdrawal period has not been established in pre-ruminating calves. Do not use in calves to be processed for veal.

ADVERSE REACTIONS: Transient inappetence, diarrhea, decreased water consumption, and injection site swelling have been associated with the use of florfenicol in cattle. In addition, anaphylaxis and collapse have been reported post-approval with the use of another formulation of florfenicol in cattle.

CLINICAL PHARMACOLOGY: The pharmacokinetic disposition of NUFLOOR GOLD® was evaluated in feeder calves following a single subcutaneous injection at a dose rate of 40 mg florfenicol/kg body weight. NUFLOOR GOLD® resulted in florfenicol plasma concentrations of 2 µg (mcg)/mL within two hours of injection.

Table 1. Pharmacokinetic Parameter Values for Florfenicol Following a Single Subcutaneous Injection of NUFLOOR GOLD® at a Dose Rate of 40 mg Florfenicol/kg Body Weight to Feeder Calves (n=24).

	C _{max} (µg/mL)	T _{max} (hr)	AUC _{last} (µg*hr/mL)	T _{1/2} (hr)
n	24	24	24	23 ²
Mean	5.93	5 ¹	150.20	37.67
% CV	38.3	2.00-12.00	20.9	27.3

C_{max}: Maximum observed plasma concentration
 T_{max}: Time at which C_{max} was observed
 AUC_{last}: Area under the curve from time zero to the last quantifiable concentration that is equal to or greater than the limit of quantification of the validated analytical method
 T_{1/2}: Terminal elimination half-life
 % CV: Percent coefficient of variance
¹ T_{max} is presented as the median value or range of observed values (minimum to maximum)
² T_{1/2} value could not be accurately estimated for one calf

MICROBIOLOGY: Florfenicol is a synthetic, broad-spectrum antibiotic active against many Gram-negative and Gram-positive bacteria isolated from domestic animals. It is primarily bacteriostatic and acts by binding to the 50S ribosomal subunit and inhibiting bacterial protein synthesis. Florfenicol is generally considered a bacteriostatic drug, but it exhibits bactericidal activity against certain bacterial species. *In vitro* studies demonstrate that florfenicol is active against the BRD pathogens *M. haemolytica*, *P. multocida*, *H. somni*, and *M. bovis* and that florfenicol exhibits bactericidal activity against strains of *M. haemolytica* and *H. somni*.

The minimum inhibitory concentrations (MICs) of florfenicol for BRD pathogens obtained from clinical trials in 2006 from cattle with naturally-occurring BRD were determined using methods recommended by the Clinical and Laboratory Standards Institute (M31-A2).

Table 2. Florfenicol MIC Values¹ of Indicated Pathogens Isolated from Cattle with Naturally-Occurring BRD

Indicated pathogens	Year of isolation	No. of isolates	MIC ₅₀ ² (µg/mL)	MIC ₉₀ ² (µg/mL)	MIC range (µg/mL)
<i>Mannheimia haemolytica</i>	2006	158	1.0	1.0	0.5 to 32
<i>Pasteurella multocida</i>	2006	103	0.5	0.5	≤ 0.125 to 16
<i>Histophilus somni</i>	2006	85	≤ 0.125	≤ 0.125	≤ 0.125 to 0.25

¹ The correlation between *in vitro* susceptibility data and clinical effectiveness is unknown.
² The MIC to encompass 50% and 90% of the isolates, respectively.

ANIMAL SAFETY: A target animal safety study was conducted to evaluate the effects of NUFLOOR GOLD® when administered to feeder cattle by subcutaneous injection at 1X, 3X, or 5X the labeled dose for three consecutive days (3X the labeled duration). Decreased feed consumption (inappetence), decreased water consumption, and injection site swelling were observed in the 1X, 3X, and 5X groups.

A separate injection site study conducted in cattle demonstrated that NUFLOOR GOLD® may induce a transient local reaction in the subcutaneous tissue and underlying muscle tissue.

STORAGE INFORMATION: Store between 2°-30°C (36°-86°F). Use within 28 days of first use. Refrigeration is not required. The solution is light yellow to straw colored. Color does not affect potency.

HOW SUPPLIED: NUFLOOR GOLD® is packaged in 100 mL (NDC 0061-5327-01), 250 mL (NDC 0061-5327-02), and 500 mL (NDC 0061-5327-03) glass sterile multiple-dose vials.

Made in Germany

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Figure 1. Mean Florfenicol Plasma Concentration versus Time Following a Single Subcutaneous Injection of NUFLOOR GOLD® at a Dose Rate of 40 mg Florfenicol/kg Body Weight in Feeder Calves (Mean ± Standard Error of the Mean)

