

Tips for Using the Nuflor® Power Doser

Consejos para usar el dosificador de potencia de Nuflor®



Preparation

- Connect Power Doser to air compressor with a 4- to 6-gallon tank.
- Set air compressor regulator at 95-100 pounds.
- Connect Power Doser to Nuflor bottle, using a draw-off tube.*
- Insert a 16-gauge, 1-inch needle. Do not over-tighten needle cap.

Administration

- Administer only by the SC (under the skin) route.
- Insert needle downward under the skin to avoid leakage.
- Pull trigger in and **hold** until the medicine chamber empties.
- You may release the trigger before or after removing the needle from the animal.
- Place no more than 10 cc in any injection site.
- If more than 10 cc is required, more than one site will be needed.

Cleaning for Next Use

- Place end of draw-off tube into gallon of vinegar (NOT WATER).
- Pump Power Doser trigger until vinegar comes out of the needle.
- Remove draw-off tube from vinegar.
- Pump trigger until no more vinegar comes out of the needle.

*Available from your Schering-Plough Animal Health representative.

Preparación

- Conecte el dosificador de potencia a un compresor de aire con un depósito de 4 a 6 galones.
- Fije el regulador del compresor de aire a 95-100 libras.
- Conecte el dosificador de potencia a la botella de Nuflor mediante un tubo de extracción.*
- Introduzca una aguja de 1 pulgada de calibre 16. No apriete excesivamente la tapa de la aguja.

Administración

- Administre solamente por vía subcutánea (debajo de la piel).
- Introduzca la aguja hacia abajo, por debajo de la piel para evitar fugas.
- Apriete el gatillo sin soltarlo hasta que se vacíe la cámara de medicamento.
- Puede soltar el gatillo antes o después de sacar la aguja del animal.
- No inyecte más de 10 cc en ningún lugar de inyección.
- Si hay que inyectar más de 10 cc, se necesitará más de un lugar.

Limpieza para el uso siguiente

- Introduzca el extremo del tubo de extracción en un galón de vinagre (NO USE AGUA).
- Bombee el gatillo del dosificador de potencia hasta que salga vinagre por la aguja.
- Saque el tubo de extracción del vinagre.
- Bombee el gatillo hasta que no salga más vinagre de la aguja.

*Solicítelo a su representante de Schering-Plough División Veterinaria.

www.nuflor.com



Do not use in female dairy cattle 20 months of age or older as use in lactating dairy cattle may cause milk residues. Not for use in cattle of breeding age. Do not use for calves to be processed for veal.

No administrar a vacas de 20 meses de edad o mayores, ya que la aplicación a vacas lecheras en lactancia puede dejar residuos en la leche. No administrar al ganado en edad reproductiva. No administrar a terneros destinados a carne de consumo.

Nuflor®
(FLORFENICOL)
HEADS UP THERAPY



F-24823121
NADA #141-063, Approved by FDA.

**PRODUCT
INFORMATION**

Nuflor[®]
(FLORFENICOL)

**Injectable Solution 300 mg/mL
For Intramuscular and Subcutaneous Use in
Cattle Only.**

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

DESCRIPTION: NUFLOR Injectable is a solution of the synthetic antibiotic florfenicol. Each milliliter of sterile NUFLOR Injectable Solution contains 300 mg of florfenicol, 250 mg n-methyl-2-pyrrolidone, 150 mg propylene glycol, and polyethylene glycol q.s.

CLINICAL PHARMACOLOGY: The pharmacokinetic disposition of NUFLOR Injectable Solution was evaluated in feeder calves following single intramuscular administration at the recommended dose of 20 mg/kg. NUFLOR Injectable Solution was also administered intravenously to the same cattle in order to calculate the volume of distribution, clearance, and percent bioavailability¹ (Table 1).

TABLE 1. Pharmacokinetic Parameter Values for Florfenicol Following IM Administration of 20 mg/kg Body Weight to Feeder Calves (n=10).

Parameter	Median	Range
C _{MAX} (µg/mL)	3.07*	1.43 - 5.60
T _{MAX} (hr)	3.33	0.75 - 8.00
T _{1/2} (hr)	18.3**	8.30 - 44.0
AUC (µg•min/mL)	4242	3200 - 6250
Bioavailability (%)	78.5	59.3 - 106
Vd _{SS} (L/kg)**	0.77	0.68 - 0.85
Cl _T (mL/min/kg)**	3.75	3.17 - 4.31

* harmonic mean
** mean value
*** following I.V. administration

C_{MAX} Maximum serum concentration
T_{MAX} Time at which C_{MAX} is observed
T_{1/2} Biological half-life

AUC Area under the curve
Vd_{SS} Volume of distribution at steady state
Cl_T Total body clearance

Florfenicol was detectable in the serum of most animals through 60 hours after intramuscular administration with a mean concentration of 0.19 µg/mL. The protein binding of florfenicol was 12.7%, 13.2%, and 18.3% at serum concentrations of 0.5, 3.0, and 16.0 µg/mL, respectively.

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. *In vitro* and *in vivo* activity has been demonstrated against commonly isolated bacterial pathogens involved in bovine respiratory disease (BRD) including *Mannheimia* (*Pasteurella*) *haemolytica*, *Pasteurella multocida*, and *Haemophilus somnus*, as well as against commonly isolated bacterial pathogens involved in bovine interdigital phlegmon including *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*.

The minimum inhibitory concentrations (MICs) of florfenicol for BRD organisms were determined using isolates obtained from natural infections from 1990 to 1993. The MICs for interdigital phlegmon organisms were determined using isolates obtained from natural infections from 1973 to 1997 (Table 2).

TABLE 2. MIC Values* of Florfenicol Against Bacterial Isolates From Natural Infection of Cattle.

Organism	Isolate Numbers	MIC ₅₀ ** (µg/mL)	MIC ₉₀ ** (µg/mL)
<i>Mannheimia</i> (<i>Pasteurella</i>) <i>haemolytica</i>	398	0.50	1.00
<i>Pasteurella multocida</i>	350	0.50	0.50
<i>Haemophilus somnus</i>	66	0.25	0.50
<i>Fusobacterium necrophorum</i>	33	0.25	0.25
<i>Bacteroides melaninogenicus</i>	20	0.25	0.25

*The correlation between the *in vitro* susceptibility data (MIC values) and clinical response has not been determined.

**The minimum inhibitory concentration for 50% and 90% of the isolates.

INDICATIONS: NUFLOR Injectable Solution is indicated for treatment of bovine respiratory disease (BRD) associated with *Mannheimia* (*Pasteurella*) *haemolytica*, *Pasteurella multocida*, and *Haemophilus somnus*, and for the treatment of bovine interdigital phlegmon (foot rot, acute interdigital necrobacillosis, infectious pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*. Also, it is indicated for the control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia* (*Pasteurella*) *haemolytica*, *Pasteurella multocida*, and *Haemophilus somnus*.

RESIDUE WARNINGS: Animals intended for human consumption must not be slaughtered within 28 days of the last intramuscular treatment. Animals intended for human consumption must not be slaughtered within 38 days of subcutaneous 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.

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, adverse effects reporting, and/or a copy of the MSDS, call 1-800-211-3573.

CAUTION: Not for use in cattle of breeding age. The effects of florfenicol on bovine reproductive performance, pregnancy, and lactation have not been determined. Intramuscular injection may result in local tissue reaction that persists beyond 28 days. This may result in trim loss of edible tissue at slaughter. Tissue reaction at injection sites other than the neck is likely to be more severe.

ADVERSE EFFECTS: Inappetence, decreased water consumption, or diarrhea may occur transiently following treatment.

TOXICOLOGY: A 10X safety study was conducted in feeder calves. Two intramuscular injections of 200 mg/kg were administered at a 48-hour interval. The calves were monitored for 14 days after the second dose. Marked anorexia, decreased water consumption, decreased body weight, and increased serum enzymes were observed following dose administration. These effects resolved by the end of the study.

A 1X, 3X, and 5X (20, 60, and 100 mg/kg) safety study was conducted in feeder calves for 3X the duration of treatment (6 injections at 48-hour intervals). Slight decrease in feed and water consumption was observed in the 1X dose group. Decreased feed and water consumption, body weight, urine pH, and increased serum enzymes were observed in the 3X and 5X dose groups. Depression, soft stool consistency, and dehydration were also observed in some animals (most frequently at the 3X and 5X dose levels), primarily near the end of dosing.

A 43-day controlled study was conducted in healthy cattle to evaluate effects of NUFLOR Injectable Solution administered at the recommended dose on feed consumption. Although a transient decrease in feed consumption was observed, NUFLOR Injectable Solution administration had no long-term effect on body weight, rate of gain, or feed consumption.

DOSAGE AND ADMINISTRATION: For treatment of bovine respiratory disease (BRD) and bovine interdigital phlegmon (foot rot): NUFLOR Injectable Solution should be administered by intramuscular injection to cattle at a dose rate of 20 mg/kg body weight (3 mL/100 lbs). A second dose should be administered 48 hours later. Alternatively, NUFLOR Injectable Solution can be administered by a single subcutaneous injection to cattle at a dose rate of 40 mg/kg body weight (6 mL/100 lbs). Do not administer more than 10 mL at each site. **The injection should be given only in the neck.**

NOTE: Intramuscular injection may result in local tissue reaction that persists beyond 28 days. This may result in trim loss of edible tissue at slaughter. Tissue reaction at injection sites other than the neck is likely to be more severe.

For control of respiratory disease in cattle at high-risk of developing BRD: NUFLOR Injectable Solution should be administered by a single subcutaneous injection to cattle at a dose rate of 40 mg/kg body weight (6 mL/100 lbs). Do not administer more than 10 mL at each site. **The injection should be given only in the neck.**

NUFLOR DOSAGE GUIDE		
ANIMAL WEIGHT (lbs)	IM NUFLOR DOSAGE 30 mL/100 lb Body Weight (mL)	SC NUFLOR DOSAGE 60 mL/100 lb Body Weight (mL)
100	3.0	6.0
200	6.0	12.0
300	9.0	18.0
400	12.0	24.0
500	15.0	30.0
600	18.0	36.0
700	21.0	42.0
800	24.0	48.0
900	27.0	54.0
1000	30.0	60.0

**Recommended
Injection Location**



Clinical improvement should be evident in most treated subjects within 24 hours of initiation of treatment. If a positive response is not noted within 72 hours of initiation of treatment, the diagnosis should be reevaluated.

STORAGE CONDITIONS: Store between 2°-30°C (36°-86°F). Refrigeration is not required. The solution is light yellow to straw colored. Color does not affect potency.

HOW SUPPLIED: NUFLOR Injectable Solution is packaged in 100 mL (NDC 0061-1116-04), 250 mL (NDC 0061-1116-05), and 500 mL (NDC 0061-1116-06) glass sterile multiple-dose vials.

REFERENCE: 1. Lobell RD, Varma KJ, et al. Pharmacokinetics of florfenicol following intravenous and intramuscular doses to cattle. *J Vet Pharmacol Therap.* 1994; 17:253-258.

Made in Germany

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TAKE TIME

