

EARLY TREATMENT KEY TO SUCCESSFUL BRD CONTROL IN CATTLE

PREPARATION AND USE OF FAST-ACTING, BROAD-SPECTRUM
ANTIBIOTIC CAN BE DIFFERENCE MAKER.

Newly weaned cattle don't always handle fluctuating temperatures and changing environments with ease, especially in the fall and winter when conditions can be more extreme. According to Dr. A.J. Tarpoff, Kansas State University Extension beef specialist, "Producers need a plan and the right products to most effectively deal with potential health problems that can arise with cattle as they arrive into feedlots."

"It all starts by working with your local veterinarian to develop a plan based on your operation and the condition of the cattle coming in," Dr. Tarpoff says. "And, it's important to have the right products on hand to treat any sick animals as soon as they are identified because we know that early treatment with effective products leads to far better outcomes."

Dr. Tarpoff notes that as part of that planning process, producers should ask their vet about treatment programs and products that will be most effective for the cattle coming in, including dosage, type of administration, withdrawal timing and efficacy.

"These are all part of the conversation producers should have before cattle arrive. In addition, the Beef Quality Assurance guidelines, available at BQA.org, are another great resource and can provide additional information to help them best manage their cattle."

"In addition to establishing protocols, selecting appropriate and effective antibiotics and administering them in a timely manner is also vital to herd health program success," says Dr. Megan Bollin, Technical Services Veterinarian for Norbrook®. She notes that



producers are more likely to encounter respiratory disease, particularly BRD (Bovine Respiratory Disease), in their herds during times of increased stress due to weather changes inherent to fall and winter, as well as related to transport, weaning, and commingling of cattle."

"Particularly in stressful situations such as these, it is imperative that herd managers carefully monitor cattle and treat sick animals at the earliest opportunity to achieve the best outcomes," explains Dr. Bollin. "As Dr. Tarpoff mentioned, the sooner producers can get sick animals treated with a fast-acting, broad-spectrum antibiotic, the better the chances are for getting that animal healthy and back into a more productive status. One antibiotic that fits this description is Norfenicol® (florfenicol) Injectable Solution."

Norfenicol® (florfenicol) Injectable Solution, the Norbrook® bioequivalent version of Nuflor® (florfenicol) Injectable Solution, has been on the market for over a decade and is labeled for the treatment and control of BRD in cattle, as well as treatment of foot rot. As Dr. Bollin explains, "Norfenicol® is differentiated from the pioneer product in several ways, having a more convenient and durable plastic hanger bottle, a more easily syringeable, less viscous formulation, and a shorter pre-slaughter withdrawal time when administered subcutaneously."

"Norfenicol® provides producers with a florfenicol antibiotic option that's much more convenient to use and administer, particularly in colder weather when product viscosity can be a problem, making treating and controlling BRD more convenient," Dr. Bollin says. "More critical for sick cattle, it's also a fast-acting antibiotic, reaching minimum inhibitory concentration (MIC) in the lungs in as little as 30 minutes¹ after injection, targeting all three bacteria that cause BRD. Together, these features make Norfenicol® a highly effective and convenient product to use in treating BRD in cattle."*

Because BRD can strike almost any time cattle are stressed, especially when weather conditions fluctuate wildly in the fall, winter and spring, Dr. Bollin advises producers to proactively work with their veterinarians in order to be prepared to treat cattle as soon as they show signs of illness. "Respiratory disease in cattle needs to be treated quickly and effectively utilizing the best resources available and that are appropriate for the situation. Norfenicol® has consistently shown to be one of the best products available for producers to use to treat and control BRD in their cattle."



¹Varma, KJ, Lockwood PW, Cosgrove MS, Rogers ER. Pharmacology, Safety and Clinical Efficacy of Nuflor (florfenicol) Following Subcutaneous Administration to Cattle. Proceedings of a Symposium Held in Conjunction with the XX World Buiatrics Congress. Sydney, Australia. July 1998: 3-19.

**Mannheimia haemolytica*, *Histophilus somni* and *Pasteurella multocida*.

Observe label directions and withdrawal times. Federal law restricts this drug to use by or on the order of a licensed veterinarian. For use in beef and non-lactating dairy cattle only. Not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Animals intended for human consumption must not be slaughtered within 28 days of the last intramuscular treatment or within 33 days of subcutaneous treatment. Do not use in calves to be processed for veal. Intramuscular injection may result in local tissue reaction which may result in trim loss at slaughter. See product labeling for full product information, including adverse reactions.

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Norfenicol®

**(florfenicol)
Injectable Solution
300 mg/mL**

For intramuscular and 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: Norfenicol® Injectable Solution is a solution of the synthetic antibiotic florfenicol. Each milliliter of sterile Norfenicol Injectable Solution contains 300 mg of florfenicol, 250 mg 2-pyrrolidone, and glycerol formal qs. The chemical name for florfenicol is *2,2-Dichloro-N-[1-(4-uoromethyl)-2-hydroxy-2-[4-(methylsulfonyl)phenyl]ethyl]acetamide*.

INDICATIONS: Norfenicol Injectable Solution is indicated for treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*, 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 haemolytica*, *Pasteurella multocida*, and *Histophilus somni*.

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

ANIMAL WEIGHT (lbs)	IM DOSAGE 3.0 mL/100 lb Body Weight (mL)	SC DOSAGE 6.0 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

Do not inject more than 10 mL per injection site.



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 re-evaluated.

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 Safety Data Sheet (SDS) contains more detailed occupational safety information. To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Norbrook at 1-866-591-5777.

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. Intramuscular injection may result in local tissue reaction which 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.

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 33 days of subcutaneous treatment. This product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established in pre-ruminating calves. Do not use in calves to be processed for veal.

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

CLINICAL PHARMACOLOGY: The pharmacokinetic disposition of florfenicol injectable solution was evaluated in feeder calves following single intramuscular (IM) administration at the recommended dose of 20 mg/kg body weight. Florfenicol injectable solution was also administered intravenously (IV) 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 _½ (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

C_{max} Maximum serum concentration

** mean value

T_{max} Time at which C_{max} is observed

*** following IV administration

T_½ 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 acts by binding to the 50S ribosomal subunit and inhibiting bacterial protein synthesis. Florfenicol is generally considered a bacteriostatic drug, but exhibits bactericidal activity against certain bacterial species. *In vitro* studies demonstrate that florfenicol is active against the bovine respiratory disease (BRD) pathogens *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*, and that florfenicol exhibits bactericidal activity against strains of *M. haemolytica* and *H. somni*. Clinical studies confirm the efficacy of florfenicol against BRD as well as against commonly isolated bacterial pathogens 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. Florfenicol Minimum Inhibitory Concentration (MIC) Values* of Indicated Pathogens Isolated from Natural Infections of Cattle.

Indicated Pathogens	Year of Isolation	Number of isolates	MIC ₅₀ ** (µg/mL)	MIC ₉₀ ** (µg/mL)
<i>Mannheimia haemolytica</i>	1990 to 1993	398	0.5	1
<i>Pasteurella multocida</i>	1990 to 1993	350	0.5	0.5
<i>Histophilus somni</i>	1990 to 1993	66	0.25	0.5
<i>Fusobacterium necrophorum</i>	1973 to 1997	33	0.25	0.25
<i>Bacteroides melaninogenicus</i>	1973 to 1997	20	0.25	0.25

* The correlation between the *in vitro* susceptibility data and clinical effectiveness is unknown.

** The lowest MIC to encompass 50% to 90% of the most susceptible isolates, respectively.

ANIMAL SAFETY: 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 florfenicol injectable solution administered at the recommended dose on feed consumption. Although a transient decrease in feed consumption was observed, florfenicol injectable solution administration had no long-term effect on body weight, rate of gain, or feed consumption.

STORAGE INFORMATION: Store at or below 77°F (25°C). Refrigeration is not required. Excursions permitted up to 86°F (30°C). Brief exposure to temperature up to 104°F (40°C) may be tolerated provided the mean kinetic temperature does not exceed 77°F (25°C); however, such exposure should be minimized. The solution is light yellow to straw colored. Color does not affect potency. Use within 28 days of first vial puncture.

HOW SUPPLIED: Norfenicol Injectable Solution is packaged in 100 mL, 250 mL, and 500 mL 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.

Restricted Drug – California. Use Only as Directed. Made in the UK.

Manufactured by: Norbrook Laboratories Limited, Newry, BT35 6PU, Co. Down, Northern Ireland.

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