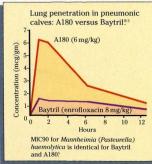
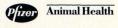


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THE BOVINE PRACTITIONER is published by the American Association of Bovine Practitioners, Inc., at Frontier Printers, 205 W. 9th, Stillwater, OK 74074 (Tel: 405-372-8500; FAX 405-372-8523). Over 6000 copies are mailed to veterinarians engaged in cattle practice and allied institutions. Send new address (please include old address) to: Dr. James A. Jarrett, Exec. Vice President, AABP, P.O. Box 1755, Rome, GA 30162-1755 Tel: 1-800-269-2227; FAX 706-232-2232 e-mail: aabphq@aabp.org

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THE BOVINE PRACTITIONER is the official publication of The American Association of Bovine Practitioners, published in February and June annually. It also serves as a communication medium between bovine practitioner organizations around the world. All manuscripts and communications must be presented in English.

Copies of THE BOVINE PRACTITIONER are available to non-members for \$25.00 per copy, surface mail, or \$33.00, airmail (overseas). Contact editor for details.

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Vol. 37, No. 2 June, 2003



Sterile Antimicrobial Injectable Solution

180.0 mg of danofloxacin as the mesylate salt/mL For subcutaneous use in cattle only

Not for use in cattle intended for dairy production or in

calves to be processed for yeal.

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

Federal law prohibits the extra-label use of this drug in food-producing animals.

INDICATIONS: A180 (danofloxacin mesylate) injectable solution is indicated for the treatment of bovine respiratory disease (BRD) associated with Mannheimia (Pasteurella) haemolytica and Pasteurella multocida.

DOSAGE AND ADMINISTRATION: A180 is administered as a subcutaneous dose of 6 mg/kg of body weight (1.5 mL/100 lb). Treatment should be repeated once approximately 48 hours following the first injection. Care should be taken to dose accurately. Administered dose volume should not exceed 15 mL per injection site.

WARNINGS: Animals intended for human consumption must not be slaughtered within 4 days from the last treatment. Do not use in cattle intended for dairy production. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

HUMAN WARNINGS: For use in animals only. Keep out of reach of children. Avoid contact with eyes. In case of contact, immediately flush eyes with copious amounts of water for 15 minutes. In case of dermal contact, wash skin with soap and water. Consult a physician if irritation persists following ocular or dermal exposures. Individuals with a history of hypersensitivity to quinolones should avoid this product. In humans, there is a risk of user photosensitization within a few hours after excessive exposure to quinolones. If excessive accidental exposure occurs, avoid direct sunlight. To report adverse reactions or to obtain a copy of the Material Safety Data Sheet, call 1-800-366-5788.

III 1-000-300-3200.

PRECAUTIONS: The effects of danofloxacin on bovine reproductive performance, pregnancy, and lactation have not been determined.

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

Quinolone-class drugs should be used with caution in animals with known or suspected central nervous system (CNS) disorders. In such animals, quinolones have, in rare instances, been associated with CNS stimulation, which may lead to convulsive seizures.

Quinolone-class drugs have been shown to produce erosions of cartilage of weight-bearing joints and other signs of arthropathy in immature, rapidly growing animals of various species. Refer to Animal Safety for information specific to danofloxacin.

ADVERSE REACTIONS: A hypersensitivity reaction was noted in 2 healthy calves treated with A180 in a laboratory study. In one location of a multi-site field trial, one out of the 41 calves treated with 6 mg/kg q 48 hours showed lameness on Day 6 only. In this same field trial location one of 38 calves treated with 8 mg/kg once became lame 4 days after treatment and remained lame on the last day of the study (Day 10). Another calf in the same treatment group developed lameness on the last day of the study.

STORAGE INFORMATION: Store at or below 30°C (86°F). Protect from light. Protect from freezing. The color is yellow to amber and does not affect potency.

HOW SUPPLIED: A180 (180 mg danofloxacin/mL) is supplied in 100- and 250-mL, amber-glass, sterile, multidose vials.

Distributed by:

NADA #141-207, Approved by FDA



Animal Health

Exton, PA 19341, USA Div. of Pfizer Inc NY, NY 10017

Use Only as Directed

To report suspected adverse effects, and/or obtain a copy of the MSDS, call 1-800-366-5288.

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The abstracts were translated in French by Guy Beauchamp and revised by Emile Bouchard.

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