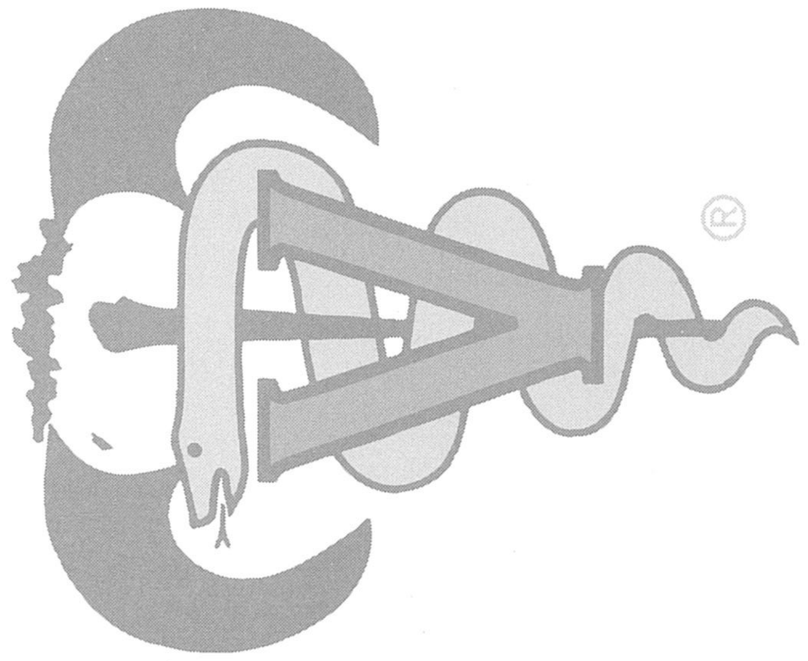

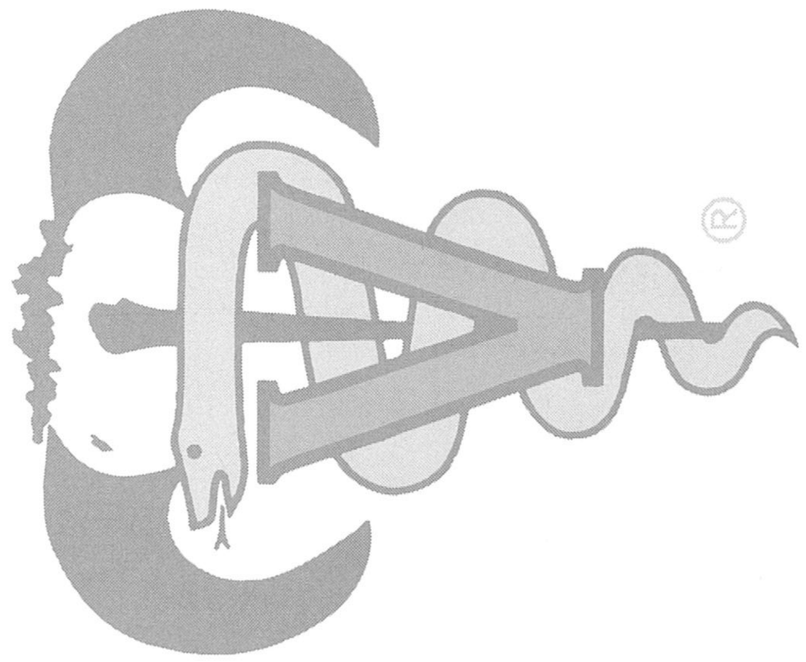

American Association of Bovine Practitioners

Prudent Drug Usage Guidelines

The production of safe and wholesome animal products for human consumption is a primary goal of members of the AABP. In reaching that goal, the AABP is committed to the practice of preventive immune system management through the use of vaccines, parasiticides, stress reduction and proper nutritional management. The AABP recognizes that proper and timely management practices can reduce the incidence of disease and therefore reduce the need for antimicrobials; however, antimicrobials remain a necessary tool to manage infectious disease in beef and dairy herds. In order to reduce animal pain and suffering, to protect the economic livelihood of beef and dairy producers, to ensure the continued production of foods of animal origin, and to minimize the shedding of zoonotic bacteria into the environment and potentially the food chain, prudent use of antimicrobials is encouraged. Following are general guidelines for the prudent therapeutic use of antimicrobials in beef and dairy cattle.

1. The veterinarian's primary responsibility to the client is to help design management, immunization, housing and nutritional programs that will reduce the incidence of disease and the need for antimicrobials.

2. Antimicrobials should be used only within the confines of a valid veterinarian-client-patient relationship; this includes both dispensing and issuance of prescriptions.

3. Veterinarians should properly select and use antimicrobial drugs.
   a. Veterinarians should participate in continuing education programs that include therapeutics and emerging and/or development of antimicrobial resistance.
   b. The veterinarian should have strong clinical evidence of the identity of the pathogen causing the disease, based upon clinical signs, history, necropsy examination, laboratory data and past experience.
   c. The antimicrobial selected should be appropriate for the target organism and should be administered at a dosage and route that are likely to achieve effective levels in the target organ.
   d. Product choices and regimens should be based on available laboratory and package insert information, additional data in the literature, and consideration of the pharmacokinetics and pharmacodynamics of the drug.
   e. Antimicrobials should be used with specific clinical outcome(s) in mind, such as fever reduction, return of mastitic milk to normal, or to reduce shedding, contagion and recurrence of disease.
   f. Periodically monitor herd pathogen susceptibility and therapeutic response, especially for routine therapy such as dry cow intramammary antibiotics, to detect changes in microbial susceptibility and to evaluate antimicrobial selections.
   g. Use products that have the narrowest spectrum of activity and known efficacy *in vivo* against the pathogen causing the disease problem.
   h. Antimicrobials should be used at a dosage appropriate for the condition treated for as short a period of time as reasonable, i.e., therapy should be discontinued when it is apparent that the immune system can manage the disease, reduce pathogen shedding and minimize recurrence of clinical disease or development of the carrier state.
   i. Antimicrobials of lesser importance in human medicine should be used in preference to newer generation drugs that may be in the same class as drugs currently used in humans if this can be achieved while protecting the health and safety of the animals.
   j. Antimicrobials labeled for use for treating the condition diagnosed should be used whenever possible. The label, dose, route, frequency and duration should be followed whenever possible.
   k. Antimicrobials should be used extra-label only within the provisions contained within AMDUCA regulations.
   l. Compounding of antimicrobial formulations should be avoided.
   m. When appropriate, local therapy is preferred over systemic therapy.
   n. Treatment of chronic cases or those with a poor chance of recovery should be avoided. Chronic cases should be removed or isolated from the remainder of the herd.
   o. Combination antimicrobial therapy should be discouraged unless there is information to show an increase in efficacy or suppression of resistance development for the target organism.
   p. Prophylactic or metaphylactic use of antimicrobials should be based on a group, source or production unit evaluation rather than being utilized as standard practice.
   q. Drug integrity should be protected through proper handling, storage and observation of the expiration date.

4. Veterinarians should endeavor to ensure proper on-farm drug use.
   a. Prescription or dispensed drug quantities should be appropriate to the production-unit size and expected need so that stockpiling of antimicrobials on the farm is avoided.
   b. The veterinarian should train farm personnel who use antimicrobials on indications, dosages, withdrawal times, route of administration, injection site precautions, storage, handling, record keeping and accurate diagnosis of common diseases. The veterinarian should ensure that labels are accurate to instruct farm personnel on the correct use of antimicrobials.
   c. Veterinarians are encouraged to provide written guidelines to clients whenever possible to describe conditions and instructions for antimicrobial use on the farm or unit.

Presented by the Bacterial Resistance and Prudent Therapeutic Antimicrobial Use Committee. Board approved March 1999.

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Hexasol® Injection
(oxytetracycline/flunixin meglumine)

I WANT HEXASOL® INJECTION

Observe label directions and withdrawal times. Not for use in female dairy cattle 20 months of age or older including dry dairy cows, bulls intended for breeding and calves intended to be processed for veal. Reports of adverse reactions associated with oxytetracycline administration include injection site swelling, restlessness, ataxia, trembling, respiratory abnormalities (labored breathing), collapse and possibly death. Some of these reactions may be attributed to anaphylaxis or to cardiovascular collapse of unknown cause. After flunixin administration, anaphylactic-like reactions have been reported, some of which have been fatal. Cyclooxygenase inhibitory NSAIDs may be associated with gastrointestinal, renal and hepatic toxicity. Concomitant use with other anti-inflammatory drugs should be avoided or closely monitored. See product labeling for full product information.

FOR VETERINARY USE ONLY

Norbrook®

www.norbrookinc.com

ANTIBIOTIC/NON-STEROIDAL ANTI-INFLAMMATORY DRUG (NSAID)
For intramuscular or subcutaneous use in beef and non-lactating dairy cattle, calves and yearlings.

Not for use in female dairy cattle 20 months of age or older, bulls intended for breeding, and calves intended to be processed for veal.

Brief Summary: Before using Hexasol Injection, please consult the product insert, a summary of which follows.

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

INDICATIONS:
For the treatment of bacterial pneumonia associated with Pasteurella spp. and for the control of associated pyrexia in beef and non-lactating dairy cattle.

CONTRAINDICATIONS: Do not use in animals showing hypersensitivity to either flunixin meglumine or oxytetracycline.

WARNINGS AND PRECAUTIONS:
Withdrawal Periods and Residue Warnings
Residue Warnings: Discontinue treatment at least 21 days prior to slaughter of cattle. Do not use in female dairy cattle 20 months of age or older. Use in this class of cattle may cause milk residues. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Use of dosages other than those indicated may result in residue violations.

Exceeding the highest recommended level of drug per pound of bodyweight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site in beef cattle and non-lactating dairy cattle may result in antibiotic residues beyond the withdrawal time.

Antibacterial Warnings
Use of antibacterial drugs in the absence of a susceptible bacterial infection is unlikely to provide benefit to treated animals and may increase the risk of the development of drug-resistant pathogenic bacteria.

User Safety Warnings
Not for use in humans. Keep out of reach of children. The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To obtain an MSDS contact Norbrook at 1-866-591-5777.

Animal Safety Warnings and Precautions
At the first sign of any adverse reaction, discontinue use of the product. Some of the reactions may be attributable either to anaphylaxis (an allergic reaction) or to cardiovascular collapse of unknown cause. Shortly after injection, treated animals may have transient hemoglobinuria resulting in darkened urine. Intramuscular injection in the rump area may cause mild temporary lameness associated with swelling at the injection site. Flunixin is a cyclo-oxygenase inhibitory NSAID, and as with others in this class, adverse effects may occur with its use. The most frequently reported adverse effects have been gastrointestinal signs. Events involving suspected renal, hematologic, neurologic, dermatologic, and hepatic effects have also been reported for other drugs in this class.

Other Warnings
Hexasol Injection, when administered as directed, may induce a transient reaction at the site of injection and underlying tissues that may result in trim loss of edible tissue at slaughter.

ADVERSE REACTIONS:
At the first sign of any adverse reaction, discontinue use of the product. Reports of adverse reactions associated with oxytetracycline administration include injection site swelling, restlessness, ataxia, trembling, swelling of eyelids, ears, muzzle, anus and vulva (or scrotum and sheath in males), respiratory abnormalities (labored breathing), frothing at the mouth, collapse and possibly death. Some of these reactions may be attributed either to anaphylaxis (an allergic reaction) or to cardiovascular collapse of unknown cause. After flunixin administration in cattle, anaphylactic-like reactions have been reported, some of which have been fatal, primarily following intravenous use.

NADA 141-312, Approved By FDA

Made in the UK.
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