## Animal Drug Use Considerations of the Bovine Practitioner

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The following paper is solely a personal opinion, not official policy of the A.A.B.P.

I heard a pharmaceutical company defined as, "an outfit that sells you medicine to eliminate stress at prices that cause it." After not speaking for four long years, the toddler son finally complained at breakfast, "Mom, the toast is burnt." His amazed mother exclaimed joyfully, "Junior, you talked!" "Well," Junior replied, "Up to now, everything has always been O.K." I wish I could say the same for the approved drugs we have to use in our own food animal practices.

The dairy practitioner is faced with a real dilemma on drug usage. We have a responsibility to the consuming public to use drugs properly, but we also have a financial responsibility to our own clients to be able to do a good job for them. I feel a great frustration in knowing that if I go strictly according to the label that almost no antibiotics are effective. I have three injectable antibiotics in my pharmacy that are approved for lactating dairy cows:

-Procaine Penicillin G, 300,000 units per ml. The label dosage for cattle, sheep, swine, and horses is 3,000 units per pound of body weight or 1 ml for each 100 pounds per body weight once daily. Penicillin is not effective at this dosage.

-Erythromycin. The label dosage is 1 to 2 mg. per pound administered once daily. I have been told by a distributor that a dosage of 5 mg. per pound has been approved, but has not been put on the label. According to literature, the effective dose is 5 to 7 mg. per pound. The problem with Erythromycin is that it is extremely irritating for intramuscular injection. We need an I.V. form.

-Ampicillin. The label dosage is 2 to 5 mg. per pound of body weight once daily. The 5 mg. dose has been an effective dose for me when it is given twice a day. If I use these three injectable antibiotics that are approved for use in lactating dairy cows at an effective dose, all three have to be used "extra label."

Penicillin Dihydrostreptomycin. is not used in my practice because of potential for residues for streptomycin. Oxytetracycline (HCL) is not approved for lactating dairy

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All the intramammary mastitis preparations are approved for sub-clinical mastitis not for clinical mastitis.

Now I want to take you out to the farm for a routine check that is scheduled for approximately three hours. When I arrive at the farm, the manager informs me that there are a number of other problems that need attention:

- acute mastitis
- two cows off feed
- one heifer that is one week past due

I examine first the cow with acute mastitis. With a temperature of 106, her right front quarter is found to be swollen and edematous. The secretion from the quarter is thin, yellow and serous in consistency with small flakes. She has diarrhea and rumen stasis. How are we going to treat this acute coliform mastitis—with 3,000 units of penicillin per pound intra muscularly once a day with with one of the intramammary mastitis preparations that are approved for sub-clinical mastitis? **NO.** I will look for "extra label" drugs. I will use oxytetracycline intravenously 6 mg. per pound and 500 mg. of gentomycin in the quarter. Have I violated the "extra label" policy?

I now begin to palpate the herd. During the examination, I find five cows that have not been observed in heat. Three have a corpus luteum that will respond to lutalyse. The three cows will be treated with prostaglandin F2 alpha (lutalyse). The label dosage of lutalyse is 25 mg. intramuscularly. Is this 25 mg. dose effective for a 1500 pound holstein? I feel it is not. I use 30 mg. which is to 5 mg. per 250 pounds of body weight.

Two of the cows have cystic ovaries. I will treat these cows with cystorelin (GnRH). Cystorelin is indicated for the treatment of ovarian follicular cysts in dairy cattle. At last I have found a drug that I am able to use as labeled! But how about the treatment of the luteal cysts or anestrus cows with small ovaries, or for cows that have been bred three or more times and need assistance in ovulation? I also use this drug for all of these veterinary problems.

I examine the heifer that is one week passed her due date. Her udder is swollen and she is dripping milk. Upon examination, I find her to have a full term calf in the normal position. The manager and I discuss the case, and we decide to induce parturition. I will use 40 mg. of lutalyse and 30 mg

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#### Lutalyse<sup>®</sup> helps make the program pay.

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"A Breeding Program for Dairy Cattle," Dr. Austin Belschner, Agri-Practice, Sept.-Oct., 1986, pg. 7-12.



of dexamethasone I.M. The heifer should have her calf in about thirty hours.

Upon examining the two cows off feed, I find that one has ketosis. I will treat this cow with 500 ml.'s of 50% dextrose I.V. and 20 mg (10 ml) of predef 2x I.M. So this cow has been treated with drugs as labeled.

After examining the second cow off feed, I find that she has a displaced abomasum. Checking my schedule, I am relieved to find that I have the time to perform the surgery during this visit. What type of anesthesia will I use? Am I going to use, "Brutocaine," since there are no tranquilizers or anesthetics approved for the dairy cow? I choose to use 5 mg. of acepromazine I.V. and a local block with lidocaine.

Am I responsible in using drugs in my food and animal practice? I feel I am. I have my clients keep logs on all treated cows and recommend use of antibiotic residue tests. Exactly how accurate are these tests? I heard recently that one test will give 100 percent false positives. A surprising finding by Dr. Jerry Jones from Virginia Polytechnic Institute, showed that 21 percent of cows treated for mastitis during lactation were not free of antibiotics in their milk by the end of the prescribed withholding period. In the study, 21 percent of the cows still had antibiotic residue in their milk one day after the prescribed withholding period. Fourteen percent of the cows still had antibiotic residues two days after the end of the withholding period: nine percent had residues three days after the end of the withholding period. We need information on the reliability of these residue tests. We need help on the withdrawal times for both milk and meat when using drugs "extra label."

We need to educate the public and especially the press that we have the most wholesome and the least expensive food supply in the world. To be able to accomplish this, I call on the Pharmaceutical Industry, the Center for Veterinary Medicine, all facets of veterinary medicine and animal industries to work together to provide food animal practitioners with new and better products for treatment of their patients so we do not have to use "extra label" treatments. If we do not, we may go back to the time when treatment of choice was whiskey and tender, loving care, but we will not be able to use whiskey, because it will be off label. I hope I have enlightened you to the problems that face the dairy practitioner when it comes to proper drug usage. The "dollar and sense" to the dairy practitioner amounts to the fact that "extra label" is the rule, not the exception when using antibiotics, tranquilizers and anesthetics, because we do not have effective or approved drugs in these groups.



#### Lutalyse<sup>®</sup> Sterile Solution (dinoprost tromethamine)

VETERINARY – For intramuscular use in cattle when regression of the corpus luteum is desired. This includes estrus synchronization, treatment of unobserved (silent) estrus and abortion of feediol and other non-lactating cattle.

#### INDICATIONS AND INSTRUCTIONS FOR USE

Cattle - Lutalyse (dinoprost tromethamine) sterile solution is indicated as a luteolytic agent.

Lutalyse is effective only in those cattle having a corpus luteum, i.e., those which ovulated at least five days prior to treatment. Future reproductive performance of animals that are not cycling will be unaffected by Lutalyse injection.

1. For Intramuscular Use for Estrus Synchronization in Beef Cattle and Non-Lactating Dairy Heifers. Lutalyse is used to control the timing of estrus and ovulation in estrus cycling cattle that have a corous luteum.

Inject a dose of 5 ml Lutalyse (25 mg  $\text{PGF}_2\alpha)$  intramuscularly either once or twice at a 10 to 12 day interval.

With the single injection, cattle should be bred at the usual time relative to estrus.

With the two injections cattle can be bred after the second injection either at the usual time relative to detected estrus or at about 80 hours after the second Lutalyse injection.

Estrus is expected to occur 1 to 5 days after injection if a corpus luteum was present. Cattle that do not become pregnant to breeding at estrus on days 1 to 5 after injection will be expected to return to estrus in about 18 to 24 days.

2. For intramuscular Use for Unobserved (Silent) Estrus in Lactating Dairy Cows with a Corpus Luteum. Inject a dose of 5 mi Lutalyse (25 mg PGF<sub>2</sub>a) intramuscularly. Breed cows as they are detected in estrus. If estrus has not been observed by 80 hours after injection, breed at 80 hours. If the cow returns to estrus breed at the usual time relative to estrus.

3. For Intramuscular Use for Treatment of Pyometra (chronic endometritis) in Cattle. Inject a dose of 5 ml Luta/yse (25 mg PGF<sub>24</sub>) intramuscularly. In studies conducted with Luta/yse, pyometra was defined as presence of a corpus luteum in the ovary and uterine horns containing fluid but not a conceptus based on palpation per rectum. Return to normal was defined as evacuation of fluid and return of the uterine horn's teo 40 mm or less based on aplapation per rectum at 14 and 28 days. Most cattle that recovered in response to Lutalyse recovered within 14 days after injection. After 14 days, recovery rate of treated cattle was no different than that of nontreated cattle.

4. For intramuscular Use for Aberlion of Feedlot and Other Non-Lactating Cattle. Lutakyse is indicated for its abortifacient effect in feedlot and other nonlactating cattle during the first 100 days of gestation. Inject a dose of 25 mg intramuscularly. Cattle that abort will abort within 35 days of injection.

#### WARNINGS

Not for human use

Women of child-bearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise **extreme caulton** when handling this product. In the early stages, women may be unaware of their pregnancies. Dinoprost tromethamine is readily absorbed through the skin and can cause abortion and/or bronchiospasms. Direct contact with the skin should, therefore, be avoided. Accidental spillage on the skin should be washed off **immediately** with scap and water.

Use of this product in excess of the approved dose may result in drug residues.

#### PRECAUTIONS

Do not administer to pregnant cattle unless abortion is desired.

Do not administer intravenously (I.V.), as this route might potentiate adverse reactions.

Cattle administered a progestogen would be expected to have a reduced response to *Lutalyse*.

Aggressive antibiotic therapy should be employed at the first sign of infection at the injection site whether localized or diffuse. As with all parenteral products careful aseptic techniques should be employed to decrease the possibility of post injection bacterial infections.

#### ADVERSE REACTIONS

 The most frequently observed side effect is increased rectal temperature at a 5x or 10x overdose. However, rectal temperature change has been transient in all cases observed and has not been detrimental to the animal.

- 2. Limited salivation has been reported in some instances
- 3. Intravenous administration might increase heart rate

 Localized post injection bacterial infections that may become generalized have been reported. In rare instances such infections have terminated fatally. See PRECAUTIONS.

#### IMPORTANT

No milk discard or preslaughter drug withdrawal period is required for labeled uses.

#### DOSAGE AND ADMINISTRATION

Lutalyse is supplied at a concentration of 5 mg dinoprost per ml. Lutalyse is luteolytic in cattle at 25 mg (5 ml) administered intramuscularly. As with any multidose vial, practice aseptic techniques in withdrawing each dose. Ade quately clean and disinfect the vial closure prior to entry with a sterile needle

#### HOW SUPPLIED

Lutalyse Sterile Solution is available in 10 and 30 ml vials.

 $\mbox{Caution: Federal (U.S.A.)}$  law restricts this drug to use by or on the order of a licensed veterinarian.



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