

delineated. For sialography slowly inject 0.5 to 1.0 milliliter into the duct to be delineated. For delineation of fistulous tracts slowly inject quantity necessary to fill the tract. For delineation of peritoneal hernias inject 0.5 to 1.0 milliliter per pound of body weight directly into the peritoneal cavity.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[44 FR 12993, Mar. 9, 1979, as amended at 50 FR 41489, Oct. 11, 1985]

**§ 522.575 Diazepam injection.**

(a) *Specification.* Each milliliter of sterile solution contains 5 milligrams of diazepam.

(b) *Sponsor.* See 000004 in § 510.600(c) of this chapter.

(c) *Conditions of use. Dogs—(1) Indications for use.* As a preanesthetic agent to reduce the amount of barbiturate required for short duration anesthesia.

(2) *Dosage.* Intravenously, 0.2 milligram per kilogram of body weight 3-5 minutes before anesthesia is to be induced using a short acting barbiturate.

(3) *Limitations.* Not for use in dogs with known sensitivity to benzodiazepines. Safety in animals intended for breeding and pregnant animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 500, Jan. 6, 1993]

**§ 522.650 Dihydrostreptomycin sulfate injection.**

(a) *Specifications.* Each milliliter contains dihydrostreptomycin sulfate equivalent to 500 milligrams of dihydrostreptomycin.

(b) *Sponsor.* See Nos. 000069 and 055529 in § 510.600(c) of this chapter.

(c) *National Academy of Sciences/National Research Council (NAS/NRC) status.* The conditions of use were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter but may require bioequivalency and safety information.

(d) *Conditions of use—(1) Amount.* 5 milligrams per pound of body weight every 12 hours.

(2) *Indications for use.* Treatment of leptospirosis in dogs and horses due to

*Leptospira canicola, L. icterohemorrhagiae, and L. pomona;* in cattle due to *L. pomona;* and in swine due to *L. pomona;* and *L. grippotyphosa.*

(3) *Limitations.* Administer by deep intramuscular injection only. Treatment should be continued for 3 to 5 days or until the urine is free of leptospira for at least 72 hours as measured by darkfield microscopic examination. Treatment with subtherapeutic dosages, excessive duration of therapy, or inappropriate use of this antibiotic may lead to the emergence of streptomycin or dihydrostreptomycin resistant organisms. Discontinue use 30 days before slaughter for food. Not for use in animals producing milk because use of the drug will contaminate the milk. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37331, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]

**§ 522.690 Dinoprost tromethamine sterile solution.**

(a) *Specifications.* Each milliliter of sterile solution contains the equivalent of 5 milligrams of dinoprost.

(b) *Sponsor.* See Nos. 000009 and 059130 in § 510.600(c) of this chapter.

(c) *Special considerations.* Women of child-bearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. Dinoprost tromethamine is readily absorbed through the skin and can cause abortion and bronchospasms. Accidental spillage on the skin should be washed off immediately with soap and water. Use of this product in excess of the approved dose may result in drug residues. Do not administer to pregnant cattle unless abortion is desired. Do not administer intravenously; this may potentiate adverse reactions.

(d) *Conditions of use—(1) Mares—(i) Amount.* Equivalent of 1 milligram of dinoprost per 100 pounds of body weight.

(ii) *Indications.* For its luteolytic effect to control timing of estrus in estrus cycling mares and in clinically anestrous mares that have a corpus luteum.

(iii) *Limitations.* For use once as a single intramuscular injection. Not for

use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle*—(i) *Amount*. 5 milliliters (equivalent to 25 milligrams of dinoprost).

(ii)(a) *Indications*. For its luteolytic effect to control timing of estrus and ovulation in estrous cycling cattle that have a corpus luteum.

(b) *Limitations*. For use in beef cattle and nonlactating dairy heifers, as follows: Inject a dose of 5 milliliters intramuscularly either once or twice at a 10- to 12-day interval. With a 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 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. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iii)(a) *Indications*. For treatment of pyometra (chronic endometritis).

(b) *Limitations*. For intramuscular use as a single injection. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Nonlactating cattle*—(i) *Amount*. Five milliliters intramuscularly as a single injection.

(ii) *Indications*. For its abortifacient effect in nonlactating cattle.

(iii) *Limitations*. For intramuscular use only, during first 100 days of gestation. Cattle that abort will abort within 35 days after injection. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Lactating dairy cattle*—(i) *Amount*. Five milliliters intramuscularly as a single injection.

(ii) *Indications*. For treatment of unobserved (silent) estrus in lactating dairy cattle that have a corpus luteum.

(iii) *Limitations*. Breed cattle as they are detected in estrus. If estrus has not been observed by 80 hours after injection, breed at 80 hours. If cattle return to estrus breed at the usual time relative to estrus. Federal law restricts

this drug to use by or on the order of a licensed veterinarian.

(5) *Swine*—(i) *Amount*. 2 milliliters (equivalent to 10 milligrams of dinoprost).

(ii) *Indications*. For parturition induction in swine when injected within 3 days of normal predicted farrowing.

(iii) *Limitations*. For use in swine as follows: Inject a dose of 2 milliliters intramuscularly within 3 days of predicted farrowing. The response to treatment varies by individual animals with a mean interval from administration to parturition of approximately 30 hours. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[41 FR 4818, Feb. 2, 1976, as amended at 46 FR 13214, Feb. 20, 1981; 46 FR 39127, July 31, 1981; 48 FR 6331, Feb. 11, 1983; 48 FR 46023, Oct. 11, 1983; 49 FR 4373, Feb. 6, 1984; 64 FR 15685, Apr. 1, 1999]

#### § 522.723 Diprenorphine hydrochloride injection.

(a) *Chemical name*. N-(Cyclopropylmethyl)-6,7,8,14-tetrahydro-7- $\alpha$ -(1-hydroxy - 1 - methylethyl) - 6,14 - endoethanonororipavine hydrochloride.

(b) *Specifications*. Each milliliter of diprenorphine hydrochloride injection, veterinary, contains 2 mg of diprenorphine hydrochloride in sterile aqueous solution.

(c) *Sponsors*. See No. 053923 in § 510.600(c) of this chapter.

(d) *Conditions of use*. (1) The drug is used for reversing the effects of etorphine hydrochloride injection, veterinary, the use of which is provided for in § 522.883, in wild and exotic animals.

(2) It is administered intramuscularly or intravenously at a suitable dosage level depending upon the species.

(3) For use in wild or exotic animals only. Do not use in domestic food-producing animals. Do not use 30 days before, or during, the hunting season in free-ranging wild animals that might be used for food.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian. Distribution is restricted to veterinarians engaged in zoo and exotic