

§ 522.690

21 CFR Ch. I (4-1-10 Edition)

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 solution.

(a) *Specifications.* Each milliliter (mL) of solution contains dinoprost tromethamine equivalent to 5 milligrams (mg) dinoprost.

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

(c) *Special considerations.* (1) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) 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 abor-

tion and bronchospasms. Accidental spillage on the skin should be washed off immediately with soap and water.

(d) *Conditions of use—(1) Horses—(i) Amount.* 1 mg per 100 pounds of body weight as a single intramuscular injection.

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

(iii) *Limitations.* Not for use in horses intended for food.

(2) *Cattle—(i) Beef cattle and nonlactating dairy heifers—(A) Amount.* 25 mg as an intramuscular injection either once or twice at a 10- to 12-day interval.

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

(ii) *Beef cattle and nonlactating dairy heifers—(A) Amount.* 25 mg as a single intramuscular injection.

(B) *Indications.* For treatment of pyometra (chronic endometritis).

(iii) *Nonlactating cattle—(A) Amount.* 25 mg as a single intramuscular injection during the first 100 days of gestation.

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

(iv) *Lactating dairy cattle—(A) Amount.* 25 mg as a single intramuscular injection.

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

(v) Dinoprost solution as provided by No. 000009 in § 510.600(c) of this chapter may be used concurrently with progesterone intravaginal inserts as in § 529.1940 of this chapter.

(3) *Swine—(i) Amount.* 10 mg as a single intramuscular injection.

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

[67 FR 41824, June 20, 2002]

§ 522.723 Diprenorphine hydrochloride injection.

(a) *Chemical name.* N-(Cyclopropylmethyl)-6,7,8,14-tetrahydro-7- α -(1-hydroxy - 1 - methylethyl) - 6,14 - endoethanonoripavine hydrochloride.