

§ 522.690

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until the urine is free of leptospira for at least 72 hours as measured by darkfield microscopic examination.

(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.* 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; 79 FR 16187, Mar. 25, 2014; 85 FR 18119, Apr. 1, 2020]

§ 522.690 Dinoprost.

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

- (1) 5 milligrams (mg) dinoprost; or
- (2) 12.5 mg dinoprost.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter as follows:

(1) Nos. 054771 and 061133 for use of product described in paragraph (a)(1) as in paragraph (d) of this section.

(2) No. 054771 for use of product described in paragraph (a)(2) as in paragraph (d)(1) of this section.

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

(d) *Conditions of use—(1) Cattle.* Administer products described in paragraph (a) of this section as follows:

(i) *Amount.* 25 mg as an intramuscular injection of the 5 mg/mL product or as an intramuscular or subcutaneous injection of the 12.5 mg/mL product.

(ii) *Indications for use.* As a luteolytic agent; effective only in those cattle having a corpus luteum, *i.e.*, those which ovulated at least 5 days prior to treatment.

(A) For estrus synchronization in beef cows, beef heifers and replacement dairy heifers.

(B) For unobserved (silent) estrus in lactating dairy cows with a corpus luteum.

(C) For treatment of pyometra (chronic endometritis) in cattle.

(D) For abortion in beef cows, beef heifers and replacement dairy heifers.

(E) For use with gonadorelin injection as in § 522.1077 of this chapter to synchronize estrous cycles to allow fixed-time artificial insemination (FTAI) in lactating dairy cows.

(F) For use with progesterone intravaginal inserts as in § 529.1940 of this chapter for synchronization of estrus in lactating dairy cows.

(G) For use with progesterone intravaginal inserts as in § 529.1940 of this chapter for synchronization of estrus in suckled beef cows and replacement beef and dairy heifers, advancement of first postpartum estrus in suckled beef cows, and advancement of first pubertal estrus in beef heifers.

(2) *Horses.* Administer product described in paragraph (a)(1) of this section as follows:

(i) *Amount.* 1 mg per 100 pounds of body weight as a single intramuscular injection.

(ii) *Indications for use.* (A) For controlling the timing of estrus in estrous cycling mares.

(B) For difficult-to-breed mares (clinically anestrus mares that have a corpus luteum).

(iii) *Limitations.* Do not use in horses intended for human consumption.

(3) *Swine.* Administer product described in paragraph (a)(1) of this section as follows:

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

(ii) *Indications for use.* For parturition induction in swine.

[67 FR 41824, June 20, 2002, as amended at 79 FR 16187, Mar. 25, 2014; 79 FR 44278, July 31, 2014; 79 FR 64116, Oct. 28, 2014; 80 FR 61296, Oct. 13, 2015; 80 FR 76386, Dec. 9, 2015; 81 FR 36789, June 8, 2016; 84 FR 8973, Mar. 13, 2019; 87 FR 17945, Mar. 29, 2022]

§ 522.723 Diprenorphine.

(a) *Specifications.* Each milliliter of solution contains 2 milligrams of diprenorphine hydrochloride.

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

(c) *Conditions of use—(1) Amount.* It is administered intramuscularly or intravenously at a suitable dosage level depending upon the species.

(2) *Indications for use.* The drug is used for reversing the effects of