

§ 529.1940 Progesterone intravaginal inserts.

(a) *Specifications.* Each insert contains:

(1) 1.38 grams (g) progesterone in molded silicone over a nylon spine.

(2) 0.3 g progesterone in molded silicone over a flexible nylon spine.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter for use of the product described in paragraph (a)(1) of this section as in paragraph (e)(1) of this section; and the product described in paragraph (a)(2) of this section as in paragraph (e)(2) of this section.

(c) *Related tolerances.* See § 556.540 of this chapter.

(d) *Special considerations*—(1) *Cows and ewes.* Product labeling shall bear the following warnings: “Avoid contact with skin by wearing protective gloves when handling inserts. Store removed inserts in a sealable container until they can be disposed of in accordance with applicable local, state, and Federal regulations.”

(2) *Cows.* This product is approved with the concurrent use of dinoprost solution when used for indications listed in paragraphs (e)(1)(ii)(A) and (e)(1)(ii)(B) of this section. See § 522.690(c) of this chapter.

(e) *Conditions of use*—(1) *Cows*—(i) *Amount.* Administer one intravaginal insert per animal for 7 days. When used for indications listed in paragraph (e)(1)(ii)(A) of this section, administer 25 milligrams (mg) dinoprost (5 milliliters (mL) of 5 mg/mL solution as in § 522.690(a) of this chapter) as a single intramuscular injection 1 day prior to insert removal (Day 6). When used for indications listed in paragraph (e)(1)(ii)(B) of this section, administer 25 mg dinoprost as a single intramuscular injection on the day of insert removal (Day 7).

(ii) *Indications for use*—(A) For synchronization of estrus in suckled beef cows and replacement beef and dairy heifers; for advancement of first postpartum estrus in suckled beef cows; and for advancement of first pubertal estrus in replacement beef heifers.

(B) For synchronization of estrus in lactating dairy cows.

(C) For synchronization of the return to estrus in lactating dairy cows in-

seminated at the immediately preceding estrus.

(D) For induction of estrous cycles in anestrous lactating dairy cows.

(iii) *Limitations.* Do not use in beef or dairy heifers of insufficient size or age for breeding or in animals with abnormal, immature, or infected genital tracts. Do not use in beef cows that are fewer than 20 days postpartum. Do not use an insert more than once. To prevent the potential transmission of venereal and bloodborne diseases, the inserts should be disposed after a single use. Administration of vaginal inserts for periods greater than 7 days may result in reduced fertility. Dinoprost solution provided by No. 054771 in § 510.600(c) of this chapter.

(2) *Ewes*—(i) *Amount.* Administer one intravaginal insert per animal for 5 days.

(ii) *Indications for use.* For induction of estrus in ewes (sheep) during seasonal anestrus.

(iii) *Limitations.* Do not use in animals with abnormal, immature, or infected genital tracts; or in ewes that have never lambed. Do not use an insert more than once. To prevent the potential transmission of venereal and bloodborne diseases, the inserts should be disposed after a single use.

[74 FR 59074, Nov. 17, 2009, as amended at 75 FR 63085, Oct. 14, 2010; 79 FR 10965, 10974, Feb. 27, 2014]

§ 529.2150 Sevoflurane.

(a) *Specifications.* Sevoflurane liquid.

(b) *Sponsors.* See Nos. 000044, 012164, and 066794 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* For induction of surgical anesthesia: up to 7 percent sevoflurane. For maintenance of surgical anesthesia: 3.7 to 4 percent sevoflurane with oxygen in the absence of premedication and 3.3 to 3.6 percent in the presence of premedication.

(2) *Indications for use.* For induction and maintenance of general anesthesia in dogs.

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

[64 FR 71640, Dec. 22, 1999, as amended at 73 FR 25508, May 7, 2008; 74 FR 10484, Mar. 11, 2009, 75 FR 1021, Jan. 8, 2010; 76 FR 16533, Mar. 24, 2011; 78 FR 17868, Mar. 25, 2013]