

§ 522.542

(2) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount*. Administer by intravenous injection as follows:

(A) *Dogs*: 0.25 to 1 mg; may be repeated for 3 to 5 days.

(B) *Horses*: 2.5 to 5 mg.

(ii) *Indications for use*. For use in dogs and horses for glucocorticoid and anti-inflammatory effect.

(iii) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[41 FR 28265, July 9, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 522.540, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 522.542 Dexamethasone suspension.

(a) *Specifications*. Each milliliter of suspension contains 1 milligram (mg) of dexamethasone-21-isonicotinate.

(b) *Sponsor*. No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Administer by intramuscular injection as follows: Dogs: 0.25 to 1 mg; cats: 0.125 to 0.5 mg; horses: 5 to 20 mg. Dosage may be repeated.

(2) *Indications for use*. For the treatment of various inflammatory conditions associated with the musculoskeletal system in dogs, cats, and horses.

(3) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16186, Mar. 25, 2014]

§ 522.558 Dexmedetomidine.

(a) *Specifications*. Each milliliter of solution contains 0.1 or 0.5 milligrams dexmedetomidine hydrochloride.

(b) *Sponsor*. See No. 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Indications for use and amount*. (A) For use as a sedative and analgesic to facilitate clinical examinations, clinical procedures, minor surgical procedures, and minor dental procedures, administer 375 micrograms (μg) per square meter ($/\text{m}^2$) of body surface area by in-

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travenous injection or 500 $\mu\text{g}/\text{m}^2$ of body surface area by intramuscular injection.

(B) For use as a preanesthetic to general anesthesia, administer 125 $\mu\text{g}/\text{m}^2$ of body surface area or 375 $\mu\text{g}/\text{m}^2$ of body surface area by intramuscular injection.

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

(2) *Cats*—(i) *Amount*. 40 $\mu\text{g}/\text{kilogram}$ by intramuscular injection.

(ii) *Indications for use*. For use as a sedative and analgesic to facilitate clinical examinations, clinical procedures, minor surgical procedures, and minor dental procedures; and as a preanesthetic to general anesthesia.

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

[72 FR 263, Jan. 4, 2007, as amended at 72 FR 19797, Apr. 20, 2007; 72 FR 51365, Sept. 7, 2007; 75 FR 60308, Sept. 30, 2010; 78 FR 25183, Apr. 30, 2013; 78 FR 33699, June 5, 2013]

§ 522.563 Diatrizoate.

(a) *Specifications*. Each milliliter of solution contains 34.3 percent diatrizoate meglumine and 35 percent diatrizoate sodium, or 66 percent diatrizoate meglumine and 10 percent diatrizoate sodium.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount*. For excretion urography, administer 0.5 to 1.0 milliliter (mL) per pound of body weight to a maximum of 30 mL intravenously. For cystography, remove urine, administer 5 to 25 mL directly into the bladder via catheter. For urethrography, administer 1.0 to 5 mL via catheter into the urethra to provide desired contrasts delineation. For angiocardiology (including aortography) rapidly inject 5 to 10 mL directly into the heart via catheter or intraventricular puncture. For cerebral angiography, rapid injection of 3 to 10 mL via carotid artery. For peripheral arteriography and/or venography and selective coronary arteriography, rapidly inject 3 to 10 mL intravascularly into the vascular bed to be delineated. For lymphography, slowly inject 1.0 to 10 mL directly into the lymph vessel to

be delineated. For arthrography, slowly inject 1.0 to 5 mL directly into the joint to be delineated. For discography, slowly inject 0.5 to 1.0 mL directly into the disc to be delineated. For sialography, slowly inject 0.5 to 1.0 mL 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 mL per pound of body weight directly into the peritoneal cavity.

(2) *Indications for use.* For visualization in excretion urography, including renal angiography, uretography, cystography, and urethrography; aortography; angiocardiology, peripheral arteriography, and venography; selective coronary arteriography; cerebral angiography; lymphography; arthrography; discography; and sialography; and as an aid in delineating peritoneal hernias and fistulous tracts.

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

[79 FR 16186, Mar. 25, 2014]

§ 522.650 Dihydrostreptomycin sulfate injection.

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

(b) *Sponsors.* See Nos. 054771 and 055529 in § 510.600(c) of this chapter.

(c) *Related tolerance.* See § 556.200 of this chapter.

(d) *Conditions of use—*(1) *Amount.* Administer 5 milligrams per pound of body weight by deep intramuscular injection every 12 hours, for 3 to 5 days or 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]

§ 522.690 Dinoprost solution.

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

(b) *Sponsors.* See Nos. 054771 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 abortion 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 estrus 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.