

**§ 522.563 Diatrizoate meglumine and diatrizoate sodium injection.**

(a) *Specifications.* Diatrizoate meglumine and diatrizoate sodium injection contains 34.3 percent diatrizoate meglumine and 35 percent diatrizoate sodium, or 66 percent diatrizoate meglumine and 10 percent diatrizoate sodium, in sterile aqueous solution.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is indicated for use in dogs and cats for visualization in excretion urography, including renal angiography, urethrography, cystography, and urethrography; aortography; angiocardiology, peripheral arteriography, and venography; selective coronary arteriography; cerebral angiography; lymphography; arthrography; discography; and sialography. It is also useful as an aid in delineating peritoneal hernias and fistulous tracts.

(2) For excretion urography administer 0.5 to 1.0 milliliter per pound of body weight to a maximum of 30 milliliters intravenously. For cystography remove urine, administer 5 to 25 milliliters directly into the bladder via catheter. For urethrography administer 1.0 to 5 milliliters via catheter into the urethra to provide desired contrasts delineation. For angiocardiology (including aortography) rapidly inject 5 to 10 milliliters directly into the heart via catheter or intraventricular puncture. For cerebral angiography rapid injection of 3 to 10 milliliters via carotid artery. For peripheral arteriography and/or venography and selective coronary arteriography rapidly inject 3 to 10 milliliters intravascularly into the vascular bed to be delineated. For lymphography slowly inject 1.0 to 10 milliliters directly into the lymph vessel to be delineated. For arthrography slowly inject 1.0 to 5 milliliters directly into the joint to be delineated. For discography slowly inject 0.5 to 1.0 milliliter directly into the disc to be 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]

**§ 522.650 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 solution.**

(a) *Specifications.* Each milliliter (mL) of solution contains dinoprost

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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 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 anestrus 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 estrus 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.

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(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- $\alpha$ -(1-hydroxy - 1 - methylethyl) - 6,14 - endoethanonoripavine 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 animal practice, wildlife management programs and researchers.

[40 FR 13858, Mar. 27, 1975, as amended at 48 FR 16241, Apr. 15, 1983; 60 FR 39847, Aug. 4, 1995; 64 FR 15684, Apr. 1, 1999]

## § 522.770 Doramectin.

(a) *Specifications*. Each milliliter of sterile aqueous solution contains 10 milligrams of doramectin.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.225 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount*. 200 micrograms per kilogram (10 milligrams per 110 pounds).

(ii) *Indications for use*. For treatment and control of gastrointestinal