

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

[66 FR 712, Jan. 4, 2001, as amended at 68 FR 34534, June 10, 2003; 68 FR 42589, July 18, 2003; 69 FR 17586, Apr. 5, 2004; 70 FR 16935, Apr. 4, 2005; 73 FR 14177, Mar. 17, 2008; 75 FR 54017, Sept. 3, 2010; 78 FR 17597, Mar. 22, 2013; 79 FR 16192, Mar. 25, 2014; 81 FR 22524, Apr. 18, 2016; 84 FR 8974, Mar. 13, 2019; 85 FR 18120, Apr. 1, 2020; 88 FR 14899, Mar. 10, 2023; 88 FR 16548, Mar. 20, 2023; 88 FR 27700, May 3, 2023; 89 FR 85427, Oct. 28, 2024]

§ 522.1696c Penicillin G procaine in oil.

(a) *Specifications.* Each milliliter contains penicillin G procaine equivalent to 300,000 units of penicillin G.

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

(c) *Conditions of use*—(1) *Amount.* Dogs and cats—10,000 units per pound of body weight once daily. Horses—3,000 units per pound of body weight once daily.

(2) *Indications for use.* Treatment of infections of dogs, cats, and horses caused by penicillin-susceptible organisms such as Streptococci, Staphylococci, and Corynebacteria.

(3) *Limitations.* Not for use in food-producing animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37333, Aug. 18, 1992, as amended at 79 FR 16193, Mar. 25, 2014]

§ 522.1698 Pentazocine.

(a) *Specifications.* Each milliliter of solution contains pentazocine lactate equivalent to 30 milligrams (mg) of pentazocine base.

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

(c) *Conditions of use*—(1) *Horses*—(i) *Amount.* Administer 0.15 mg pentazocine base per pound of body weight daily by intravenous or intramuscular injection. In cases of severe pain, a second dose is recommended by intramuscular injection 10 to 15 minutes after the initial dose at the same level.

(ii) *Indications for use.* For symptomatic relief of pain due to colic.

(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.

(2) *Dogs*—(i) *Amount.* Administer 0.75 to 1.50 mg of pentazocine base per pound of body weight by intramuscular injection.

(ii) *Indications for use.* For amelioration of pain accompanying post-operative recovery, fracture, trauma, and spinal disorders.

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

[42 FR 31450, June 21, 1977, as amended at 42 FR 36995, July 19, 1977; 47 FR 5409, Feb. 5, 1982; 55 FR 23076, June 6, 1990; 79 FR 16193, Mar. 25, 2014. Redesignated at 86 FR 61685, Nov. 8, 2021, and further redesignated at 88 FR 14899, Mar. 10, 2023]

§ 522.1700 Pentobarbital and phenytoin.

(a) *Specifications.* Each milliliter (mL) of solution contains 390 milligrams (mg) pentobarbital sodium and 50 mg phenytoin sodium.

(b) *Sponsors.* See Nos. 000061, 051311, 054925, and 086119 in § 510.600(c) of this chapter.

(c) *Special considerations.* Product labeling shall bear the following warning statements: “ENVIRONMENTAL HAZARD: This product is toxic to wildlife. Birds and mammals feeding on treated animals may be killed. Euthanized animals must be properly disposed of by deep burial, incineration, or other method in compliance with State and local laws, to prevent consumption of carcass material by scavenging wildlife.”

(d) *Conditions of use in dogs*—(1) *Amount.* Administer 1 mL per 10 pounds of body weight as a single, bolus intravenous or intracardiac injection.

(2) *Indications for use.* For humane, painless, and rapid euthanasia.

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

[85 FR 18120, Apr. 1, 2020, as amended at 85 FR 45308, July 28, 2020. Redesignated at 86 FR 61685, Nov. 8, 2021; 88 FR 84701, Dec. 6, 2023]

§ 522.1703 Pentobarbital.

(a) *Specifications.* Each milliliter of solution contains 64.8 milligrams (mg) of sodium pentobarbital.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

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(c) *Conditions of use*—(1) *Amount*. The drug is administered intravenously “to effect”. For general surgical anesthesia, the usual dose is 11 to 13 mg per pound of body weight. For sedation, the usual dose is approximately 2 mg per pound of body weight. For relieving convulsive seizures caused by strychnine in dogs, the injection should be administered intravenously “to effect”. The drug may be administered intraperitoneally. When given intraperitoneally, it is administered at the same dosage level as for intravenous administration.

(2) *Indications for use*. The drug is indicated for use as a general anesthetic in dogs and cats. Although it may be used as a general surgical anesthetic for horses, it is usually given at a lower dose to cause sedation and hypnosis and may be supplemented with a local anesthetic. It may also be used in dogs for the symptomatic treatment of strychnine poisoning.

(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 16193, Mar. 25, 2014. Redesignated at 86 FR 61685, Nov. 8, 2021]

§ 522.1704 Pentosan polysulfate sodium.

(a) *Specifications*. Each milliliter of solution contains 250 milligrams (mg) of pentosan polysulfate sodium.

(b) *Sponsor*. See No. 043264 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Administer 3 mg per kilogram of body weight (1.4 mg per pound) by intramuscular injection once weekly for 4 weeks for a total of four doses.

(2) *Indications for use*. For the control of clinical signs associated with osteoarthritis in horses.

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

[88 FR 16548, Mar. 20, 2023, as amended at 88 FR 84701, Dec. 6, 2023]

§ 522.1720 Phenylbutazone.

(a) *Specifications*. (1) Each milliliter of solution contains 100 milligrams (mg) of phenylbutazone.

(2) Each milliliter of solution contains 200 mg of phenylbutazone.

(b) *Sponsors*. See sponsor numbers in § 510.600(c) of this chapter for use as in paragraph (c) of this section:

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

(2) Nos. 000061, 054771, 058198, and 061133 for use of product described in paragraph (a)(2) of this section as in paragraph (c) of this section.

(3) Nos. 058005 and 069043 for use of product described in paragraph (a)(2) as in paragraph (c)(2) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Administer by intravenous injection 10 mg per pound of body weight daily in three divided doses, not to exceed 800 mg daily regardless of weight. Limit intravenous administration to 2 successive days. Oral medication may follow.

(ii) *Indications for use*. It is used for the relief of inflammatory conditions associated with the musculoskeletal system.

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

(2) *Horses*—(i) *Amount*. Administer by intravenous injection 1 to 2 grams (g) per 1,000 pounds of body weight daily in three divided doses, not to exceed 4 g daily. Limit intravenous administration to not more than 5 successive days.

(ii) *Indications for use*. For the relief of inflammatory conditions associated with the musculoskeletal system.

(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.

[79 FR 16193, Mar. 25, 2014, as amended at 83 FR 48946, Sept. 28, 2018; 84 FR 8974, Mar. 13, 2019; 86 FR 14820, Mar. 19, 2021]

§ 522.1820 Pituitary luteinizing hormone powder for injection.

(a) *Specifications*. The drug is a lyophilized pituitary extract. Each 6-milliliter vial contains an amount equivalent to 25 milligrams of standard pituitary luteinizing hormone and is reconstituted for use by addition of 5 milliliters of 0.9 percent aqueous sodium chloride solution.