

§ 522.1885

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and continued for 3 to 5 days if necessary. If permanent corticosteroid effect is required oral therapy with prednisolone tablets may be substituted.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13858, Mar. 27, 1975, as amended at 46 FR 13215, Feb. 20, 1981; 46 FR 33513, June 30, 1981; 52 FR 25212, July 6, 1987; 66 FR 23588, May 9, 2001]

§ 522.1885 Prednisolone tertiary butylacetate suspension.

(a) *Specifications.* Prednisolone tertiary butylacetate (Pregna-1,4-diene-3, 20-dione-11B, 17 α 21-triol 21-(3,3, dimethyl butyrate) suspension contains 20 milligrams of prednisolone tertiary butylacetate per milliliter. It is sterile.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used as an anti-inflammatory agent in horses, dogs, and cats.¹

(2) It is administered to horses intramuscularly at a dosage level of 100 to 300 milligrams and intrasynovially at a dosage level of 50 to 100 milligrams. It is administered intramuscularly to dogs and cats at a dosage level of 1 milligram per 5 pounds of body weight and intrasynovially at a dosage level of 10 to 20 milligrams. Intramuscular retreatment of horses in 24 to 48 hours may be necessary, depending on the general condition of the animal and the severity and duration of the disease.¹

(3) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered late in pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.¹

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13858, Mar. 27, 1975, as amended at 62 FR 63271, Nov. 28, 1997]

§ 522.1890 Sterile prednisone suspension.

(a) [Reserved]

(b)(1) *Specifications.* Each milliliter of sterile aqueous suspension contains 10 to 40 milligrams of prednisone.

(2) *Sponsor.* See 000061 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount.* Administer intramuscularly as follows:

(a) *Horses.* 100 to 400 milligrams, repeating if necessary. If no response is observed after 3 to 4 days of therapy, reevaluate diagnosis.¹

(b) *Dogs and cats.* 0.25 to 1.0 milligram per pound of body weight for 3 to 5 days or until a response is noted. Treatment may be continued with an orally administered dose.¹

(ii) *Indications for use.* It is used for conditions requiring an anti-inflammatory agent.¹

(iii) *Limitations.*¹ Do not use in viral infections. Except in emergency therapy, do not use in animals with tuberculosis, chronic nephritis, or Cushing's disease. With infections, use appropriate antibacterial therapy with and for at least 3 days after discontinuance of use and disappearance of all signs of infection. Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 13446, Feb. 29, 1980, as amended at 50 FR 6160, Feb. 14, 1985; 52 FR 7832, Mar. 13, 1987]

§ 522.1920 Prochlorperazine, isopropamide for injection.

(a) *Specifications.* Prochlorperazine, isopropamide for injection, veterinary, contains in each milliliter, 6 milligrams of prochlorperazine edisylate (equivalent to 4 milligrams prochlorperazine), and 0.38 milligrams of isopropamide iodide (equivalent to

¹These conditions are NAS/NRC reviewed and deemed 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.