Food and Drug Administration, HHS

§ 522.1883 Prednisolone sodium phosphate.

(a) Specifications. Each milliliter of solution contains 20 milligrams (mg) prednisolone sodium phosphate (equivalent to 14.88 mg of prednisolone).

(b) Sponsor. See No. 061623 in § 510.600(c) of this chapter.

(c) Conditions of use in dogs—(1) Amount. Administer intravenously in a dosage of 2½ to 5 mg per pound of body weight, initially for shock and shock-like states, followed by equal maintenance doses at 1-, 3-, 6-, or 10-hour intervals as determined by the condition of the animal.

(2) Indications for use. Administer when a rapid adrenal glucocorticoid and/or anti-inflammatory effect is necessary.

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

[68 FR 59881, Oct. 20, 2003]

§ 522.1884 Prednisolone sodium succinate injection.

(a) Chemical name. 11 beta, 17, 21-Trihydroxypregna-1, 4-diene-3, 20-dione 21-succinate sodium salt.

(b) Specifications. Each milliliter of prednisolone sodium succinate injection contains: Prednisolone sodium succinate equivalent in activity to 10, 20, or 50 milligrams of prednisolone.

(c) Sponsor. See No. 000009 in § 510.600(c) of this chapter for products containing 10, 20, and 50 milligrams equivalent prednisolone activity per milliliter for use in horses, dogs, and cats as provided in paragraphs (d)(1), (2)(i), (ii), and (iii) of this section.

(d) Conditions of use. (1) The drug is intended for the treatment of horses, dogs, and cats.

(2)(i) The dosage for horses is 50 to 100 milligrams as an initial dose given intravenously over a period of one-half to 1 minute, or intramuscularly, and may be repeated in inflammatory, allergic, or other stress conditions at intervals of 12, 24, or 48 hours, depending upon the size of the animal, the severity of the condition and the response to treatment.

(ii) In dogs, the drug is administered intravenously at a range of 2.5 to 5 milligrams per pound of body weight as an initial dose followed by maintenance doses at 1, 3, 6, or 10 hour intervals, as determined by the condition of the animal, for treatment of shock.

(iii) In dogs and cats, the drug may be given intramuscularly for treatment of inflammatory, allergic and less severe stress conditions, where immediate effect is not required, at 1 to 5 milligrams ranging upward to 30 to 50 milligrams in large breeds of dogs. Dosage may be repeated in 12 to 24 hours

1These conditions are 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.
§ 522.1885  Prednisolone tertiary butylacetate suspension.

(a) Specifications. Prednisolone tertiary butylacetate 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 re-treatment 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 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.1


§ 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

[40 FR 13858, Mar. 27, 1975, as amended at 62 FR 6160, Nov. 28, 1997]