§ 522.1881 Sterile prednisolone acetate aqueous suspension.

(a) Specifications. Each milliliter of sterile aqueous suspension contains 25 milligrams of prednisolone acetate.

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

(c) NAS/NRC status. The conditions of use are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in § 514.111 of this chapter but may require bioequivalency and safety information.

(d) Conditions of use. (1) The drug is indicated in the treatment of dogs, cats, and horses for conditions requiring an anti-inflammatory agent. The drug is indicated for the treatment of acute musculoskeletal inflammations such as bursitis, carpitis, and spondylitis. The drug is indicated as supportive therapy in nonspecific dermatosis such as summer eczema and atopy. The drug may be used as supportive therapy pre- and post-operatively and for various stress conditions when corticosteroids are required while the animal is being treated for a specific condition.

(2) The drug is administered to horses intra-articularly at a dosage level of 50 to 100 milligrams. The dose may be repeated when necessary. If no response is noted after 3 or 4 days, the possibility must be considered that the condition is unresponsive to prednisolone therapy. The drug may be given intra-articularly to dogs and cats at a dosage level of 5 to 25 milligrams. The dose may be repeated when necessary after 7 days for two or three doses.

(3) The labeling shall comply with the requirements of § 510.410 of this chapter for corticosteroids.

(4) Not for use in horses intended for food.

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

§ 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 2 1/2 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.

§ 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.

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.
Food and Drug Administration, HHS

§ 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 No. 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.

(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.

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

(iii) Limitations. Do not use in viral infections. Except in emergency therapy, do not use in animals with tuberculosis, chronic nephritis, or Cushings’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

1 These 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.