

by or on the order of a licensed veterinarian.

[54 FR 50365, Dec. 6, 1989; 54 FR 51551, Dec. 15, 1989]

**§ 522.540 Dexamethasone injection.**

(a)(1) *Specifications.* Each milliliter of solution contains 2 milligrams (mg) dexamethasone.

(2) *Sponsors.* See sponsors in § 510.600(c) of this chapter:

(i) Nos. 000061, 059130, and 061623 for use as in paragraph (a)(3) of this section.

(ii) No. 058005 for use as in paragraphs (a)(3)(i)(C), (a)(3)(i)(D), (a)(3)(ii)(A), and (a)(3)(iii) of this section.

(3) *Conditions of use—(i) Amount.* The drug is administered intravenously or intramuscularly and dosage may be repeated if necessary, as follows:

(A) *Dogs.* 0.25 to 1 mg.

(B) *Cats.* 0.125 to 0.5 mg.

(C) *Horses.* 2.5 to 5 mg.

(D) *Cattle.* 5 to 20 mg, depending on the severity of the condition.

(ii) *Indications for use.* The drug is indicated:

(A) For the treatment of primary bovine ketosis and as an anti-inflammatory agent in cattle and horses;

(B) As an anti-inflammatory agent in dogs and cats.

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

(b)(1) *Specifications.* The drug is a sterile aqueous solution. Each milliliter contains either 2.0 milligrams of dexamethasone or 4.0 milligrams of dexamethasone sodium phosphate (equivalent to 3.0 milligrams dexamethasone).

(2) *Sponsor.* See number in § 510.600(c) of this chapter as follows:

(i) No. 061623 for use of 2.0 milligrams dexamethasone or 4.0 milligrams dexamethasone sodium phosphate injections.

(ii) No. 000402 for use of 2.0 milligrams dexamethasone or 4.0 milligrams dexamethasone sodium phosphate injections.

(3) *Conditions of use.* (i) The drug is used in dogs for the treatment of inflammatory conditions, as supportive therapy in canine posterior paresis, as supportive therapy before or after surgery to enhance recovery of poor sur-

gical risks, and as supportive therapy in nonspecific dermatosis.<sup>1</sup>

(ii) The drug is administered intravenously at 0.25 to 1 milligram initially. The dose may be repeated for 3 to 5 days or until a response is noted. If continued treatment is required, oral therapy may be substituted. When therapy is withdrawn after prolonged use, the daily dose should be reduced gradually over several days.<sup>1</sup>

(iii) 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.

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

(c)(1) *Specifications.* The drug is a sterile aqueous solution. Each milliliter contains 2.0 milligrams of dexamethasone or 4.0 milligrams of dexamethasone sodium phosphate (equivalent to 3.0 milligrams of dexamethasone).

(2) *Sponsor.* See Nos. 000402 and 061623 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is used as a rapid adrenal glucocorticoid and/or anti-inflammatory agent in horses.<sup>1</sup>

(ii) The drug is administered intravenously at a dosage of 2.5 to 5.0 milligrams. If permanent corticosteroid effect is required, oral therapy may be substituted. When therapy is withdrawn after prolonged use, the daily dose should be reduced gradually over several days.<sup>1</sup>

(iii) 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.

<sup>1</sup>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.

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

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

(d)(1) *Specifications.* The drug is a sterile aqueous solution. Each milliliter contains 2.0 milligrams of dexamethasone or 4.0 milligrams of dexamethasone sodium phosphate (equivalent to 3.0 milligrams of dexamethasone).

(2) *Sponsors.* See the following numbers in §510.600(c) of this chapter:

(i) Nos. 000069 and 059130 for intravenous or intramuscular use of 2.0 milligrams dexamethasone injection.

(ii) No. 000069 for intravenous use of 2.0 milligrams dexamethasone injection.

(3) *Conditions of use.* (i) The drug is used as an anti-inflammatory agent in dogs, cats, and horses.

(ii) It is administered intravenously or intramuscularly as follows: dogs—0.25 to 1 milligram; cats—0.125 to 0.5 milligram; horses—2.5 to 5 milligrams.

(iii) Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection 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.

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

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

(e)(1) *Specifications.* The drug is a sterile aqueous solution. Each milliliter contains 4.0 milligrams of dexamethasone sodium phosphate (equivalent to 3 milligrams of dexamethasone).

(2) *Sponsor.* See No. 059130 in §510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is given for glucocorticoid and anti-inflammatory effect in dogs and horses.

(ii) Administer intravenously as follows: Dogs—0.25 to 1 milligram initially; may be repeated for 3 to 5 days or until response is noted. Horses—2.5 to 5 milligrams. If permanent glucocorticoid effect is required, oral therapy may be substituted. When

therapy is to be withdrawn after prolonged use, the daily dose should be reduced gradually over several days.

(iii) Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection 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.

(iv) Do not use in viral infections. Anti-inflammatory action of corticosteroids may mask signs of infections. Except when used for emergency therapy, the product is contraindicated in animals with tuberculosis, chronic nephritis, cushingoid syndrome, or peptic ulcers.

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

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

[41 FR 28265, July 9, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 522.540, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

#### § 522.542 Dexamethasone-21-isonicotinate suspension.

(a) *Specifications.* Each milliliter of sterile suspension contains 1 milligram of dexamethasone-21-isonicotinate.

(b) *Sponsor.* No. 000010 in §510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in the treatment of various inflammatory conditions associated with the musculoskeletal system in dogs, cats, and horses.

(2) It is recommended for intramuscular administration as follows: Dogs—0.25 to 1 milligram; cats—0.125 to 0.5 milligram; horses—5 to 20 milligrams. Dosage may be repeated.

(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 following by dystocia, fetal death, retained placenta, and metritis.