

§ 520.540b

21 CFR Ch. I (4-1-00 Edition)

§ 520.540b Dexamethasone tablets and boluses.

(a)(1) *Specifications.* Each bolus is half-scored and contains 10 milligrams of dexamethasone.

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

(3) *Conditions of use.* (i) Dexamethasone bolus is indicated in cases where cattle and horses require additional steroid therapy following its parenteral administration. The drug may be used as supportive therapy for management of inflammatory conditions such as acute arthritic lamenesses, and for various stress conditions where corticosteroids are required while the animal is being treated for a specific condition.

(ii) Administered orally, 5 to 10 milligrams for the first day, then 5 milligrams per day as required.

(iii) Do not use in viral infections during the viremic stage. With bacterial infections, appropriate antibacterial therapy should be used.

(iv) Do not use in animals with chronic nephritis and hypercorticalism (Cushingoid syndrome), except for emergency therapy.

(v) 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.

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

(b)(1) *Specifications.* Each tablet contains 0.25 milligram of dexamethasone.¹

(2) *Sponsors.* See Nos. 000061 and 050604 in § 510.600(c) of this chapter.

(3) *Conditions of use—(i) Amount.* Dogs: Administer orally at 0.25 to 1.25 milligrams per day for up to 7 days. Cats: 0.125 to 0.5 milligram per day for up to 7 days.¹

(ii) *Indications for use.* In treatment of dogs and cats as an anti-inflammatory agent.¹

(iii) *Limitations.* (a) 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 they may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(b) Do not use in viral infections. Anti-inflammatory action of corticosteroids may mask signs of infections. Do not use in animals with tuberculosis, chronic nephritis, Cushingoid syndrome, or peptic ulcers, except for emergency therapy.¹

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

[40 FR 26273, June 23, 1975, as amended at 44 FR 7130, Feb. 6, 1979; 50 FR 49372, Dec. 2, 1985; 52 FR 7832, Mar. 13, 1987; 55 FR 8461, Mar. 8, 1990]

§ 520.540c Dexamethasone chewable tablets.

(a) *Specifications.* Each half-scored tablet contains 0.25 milligram of dexamethasone.¹

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* 0.25 to 1.25 milligrams per day.¹

(2) *Indications for use.* Supportive therapy in nonspecific dermatosis and inflammatory conditions in dogs.¹

(3) *Limitations.* (i) Administer by free-choice feeding or crumble over food. Administer 0.25 to 1.25 milligrams daily in single or two divided doses until response is noted or 7 days have elapsed. When response is attained, dosage should be gradually reduced by 0.125 milligram per day until maintenance level is achieved.

(ii) 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 they may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

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.

(iii) Do not use in viral infections. Anti-inflammatory action of corticosteroids may mask signs of infection. Do not use in animals with tuberculosis, chronic nephritis, cushingoid syndrome, or peptic ulcers, except for emergency therapy.¹

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

[44 FR 7130, Feb. 6, 1979, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.550 Dextrose/glycine/electrolyte.

(a) *Specifications.* The product is distributed in packets each of which contains the following ingredients: sodium chloride 8.82 grams, potassium phosphate 4.20 grams, citric acid anhydrous 0.5 gram, potassium citrate 0.12 gram, aminoacetic acid (glycine) 6.36 grams, and dextrose 44.0 grams.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) Dextrose/glycine/electrolyte is indicated for use in the control of dehydration associated with diarrhea (scours) in calves. It is used as an early treatment at the first signs of scouring. It may also be used as followup treatment following intravenous fluid therapy.

(2) Dissolve each packet in two quarts of warm water and administer to each calf as follows:

(i) *Scouring and/or dehydrated calves.* Feed 2 quarts of solution, twice daily for 2 days (four feedings). No milk or milk replacer should be fed during this period. For the next four feedings (days 3 and 4), use 1 quart of solution together with 1 quart of milk replacer. Thereafter, feed as normal.

(ii) *Newly purchased calves.* Feed 2 quarts of solution instead of milk as the first feed upon arrival. For the next scheduled feeding, use 1 quart of solution mixed together with 1 quart of milk or milk replacer. Thereafter, feed as normal.

(3) The product should not be used in animals with severe dehydration (down, comatose, or in a state of shock). Such animals need intravenous therapy. Oral therapy in these cases is too slow. Animals which cannot drink after initial intravenous therapy may need to be dosed with a stomach tube or esophageal tube. Adequate colos-

trum intake during the first 12 hours is essential for healthy, vigorous calves. Antibacterial therapy is often indicated in bacterial scours due to *E. coli* and/or *Salmonella*. The product does not contain antibacterial agents. A veterinarian should be consulted in severely scouring calves or cases requiring antibacterial therapy. The product is not nutritionally complete if administered by itself for long periods of time. It should not be administered beyond the recommended treatment period without the addition of milk or milk replacer.

[48 FR 38606, Aug. 25, 1983, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.563 Diatrizoate meglumine and diatrizoate sodium oral solution.

(a) *Specifications.* Diatrizoate meglumine oral solution is a water soluble radiopaque medium containing 66 percent diatrizoate meglumine and 10 percent diatrizoate sodium.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is indicated for radiography of the gastrointestinal tract in dogs and cats.

(2) It is administered orally at a dosage level of 0.5 to 1.0 milliliter per pound of body weight by gavage or stomach tube. It is administered rectally at a dosage level of 0.5 to 1.0 milliliter per pound of body weight diluted with 1 part of the drug to 5 parts of water.

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

[44 FR 12993, Mar. 9, 1979, as amended at 50 FR 41489, Oct. 11, 1985]

§ 520.580 Dichlorophene and toluene capsules.

(a) *Specifications.* Each soft gelatin capsule contains 50 milligrams of dichlorophene and 60 milligrams of toluene or multiples thereof.¹

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.