

Food and Drug Administration, HHS

§ 520.540b

(b) *Sponsor*. See No. 046573 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.170 of this chapter.

(d) *Conditions of use. Calves*—(1) *Amount*. Feed 22.7 milligrams per 100 pounds of body weight (0.5 milligram per kilogram) per day.

(2) *Indications for use*. For the prevention of coccidiosis in ruminating and nonruminating calves, including veal calves, caused by *Eimeria bovis* and *E. zuernii*.

(3) *Limitations*. Feed in whole milk at the rate of 22.7 milligrams per 100 pounds body weight daily (0.5 milligram per kilogram) for at least 28 days.

[64 FR 10103, Mar. 2, 1999, as amended at 64 FR 30386, June 8, 1999]

§ 520.540 Dexamethasone oral dosage forms.

§ 520.540a Dexamethasone powder.

(a) *Specifications*. Dexamethasone powder is packaged in packets containing 10 milligrams of dexamethasone.

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

(c) *Conditions of use*. (1) Dexamethasone powder is indicated in cases where cattle and horses require additional steroid therapy following its parenteral administration. The drug is used as supportive therapy for management or inflammatory conditions such as acute arthritic lameness, and for various stress conditions where corticosteroids are required while the animal is being treated for a specific condition.

(2) The drug is administered at a dosage level of 5 to 10 milligrams per animal the first day then 5 milligrams per day as required by drench or by sprinkling on a small amount of feed.

(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.

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

[40 FR 13838, Mar. 27, 1975; 41 FR 9149, Mar. 3, 1976; 52 FR 7832, Mar. 13, 1987]

§ 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 061133 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

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(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; 66 FR 14073, Mar. 9, 2001]

§ 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.

(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

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.