Food and Drug Administration, HHS

§ 520.540b Dexamethasone tablets and boluses.

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

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


§ 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) [Reserved]

(d) 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. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

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