

§ 520.1408

(2) Dosage is based upon severity of symptoms and response noted. The usual initial dose in 60 milligrams per pound of body weight in two or three equally divided doses followed by 30 to 60 milligrams per pound of body weight each following day, usually not to exceed 14 to 21 days.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 67 FR 67521, Nov. 6, 2002]

§ 520.1408 Methylprednisolone tablets.

(a) *Specifications.* Each table contains 1, 2, or 4 milligrams of methylprednisolone.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter for use of 1- and 4-milligram tablets; see No. 000010 for use of 1- and 2-milligram tablets.

(c) *NAS/NRC status.* The conditions of use have been NAS/NRC reviewed and found effective. NADA's for approval of drugs for these conditions of use need not include effectiveness data specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Special consideration.* (1) 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.

(2) Systemic therapy with methylprednisolone is contraindicated in animals with arrested tuberculosis, peptic ulcer, acute psychoses, or cushingoid syndrome. The presence of active tuberculosis, diabetes, osteoporosis, chronic psychotic reactions, predisposition to thrombophlebitis, hypertension, congestive heart failure, or renal insufficiency necessitates carefully controlled use of corticosteroids. Some of these conditions occur only rarely in dogs and cats but should be kept in mind.

(3) Anti-inflammatory action of corticosteroids may mask signs of infection.

(e) *Conditions of use*—(1) *Amount.* Dogs and cats: 5 to 15 pounds, 2 milligrams;

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15 to 40 pounds, 2 to 4 milligrams; 40 to 80 pounds, 4 to 8 milligrams.

(2) *Indications for use.* For use in dogs and cats as an anti-inflammatory agent.

(3) *Limitations.* Administer total daily dose orally in equally divided doses 6 to 10 hours apart until response is noted or 7 days have elapsed. When response is attained, dosage should be gradually reduced until maintenance level is achieved. Hazardous for human use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 52697, Nov. 23, 1982, as amended at 49 FR 20810, May 17, 1984; 50 FR 32844, Aug. 15, 1985; 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997]

§ 520.1409 Methylprednisolone, aspirin tablets.

(a) *Specifications.* Each tablet contains 0.5 milligram of methylprednisolone and 300 milligrams of aspirin.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *NAS/NRC status.* The conditions of use have been NAS/NRC reviewed and found effective. New animal drug applications for approval of drugs for these conditions of use need not include effectiveness data specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Special considerations.* (1) 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.

(2) Systemic therapy with methylprednisolone is contraindicated in animals with tuberculosis, chronic nephritis, peptic ulcer, or Cushingoid syndrome. The presence of diabetes mellitus, osteoporosis, predisposition to thrombophlebitis, hypertension, congestive heart failure, or renal insufficiency necessitates carefully controlled use of corticosteroids.

(3) Anti-inflammatory action of corticosteroids may mask signs of infection.

(e) *Conditions of use*—(1) *Amount*. Dogs under 15 pounds, ¼ to 1 tablet daily; 15 to 60 pounds, 1 to 2 tablets daily; 60 pounds and over, 2 tablets daily.

(2) *Indications for use*. As an anti-inflammatory and analgesic agent in dogs.

(3) *Limitations*. Administer total daily dose in divided doses 6 to 10 hours apart, with a light feeding. When response is attained, dosage should be gradually reduced until maintenance level is achieved. Do not administer to cats. Do not overdose. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 21566, May 13, 1983]

§ 520.1422 Metoserpate hydrochloride.

(a) *Chemical name*. Methyl-*o*-methyl-18-epireserpate hydrochloride.

(b) *Sponsor*. See No. 000003 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.410 of this chapter.

(d) *Conditions of use*. It is used in drinking water for replacement chickens as follows:

(1) *Amount*. 568.5 milligrams per gallon (0.015 percent).

(i) *Indications for use*. As a tranquilizer for flock treatment of chickens prior to handling.

(ii) *Limitations*. To be used one time as a treatment for replacement chickens up to 16 weeks of age; usual drinking water should be withheld prior to treatment to provide adequate consumption of medicated drinking water; not for use in laying chickens; chickens slaughtered within 72 hours following treatment must not be used for food.

(2) *Amount*. 2 to 4 milligrams per 2.2 pounds of body weight.

(i) *Indications for use*. As an aid in control of hysteria.

(ii) *Limitations*. To be used as a treatment for replacement chickens up to 16 weeks of age; usual drinking water should be withheld prior to treatment to provide adequate consumption of medicated drinking water; the drug should be administered at a dosage level of 4 milligrams per 2.2 pounds of body weight followed by 2 treatments at 4-day intervals of 2 milligrams per 2.2 pounds of body weight; not for use in laying chickens; chickens slaugh-

tered within 72 hours following treatment must not be used for food.

§ 520.1430 Mibolerone.

(a) *Specifications*. Each milliliter contains 100 micrograms of mibolerone.

(b) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. 30 micrograms for animals weighing 1 to 25 pounds; 60 micrograms for animals weighing 26 to 50 pounds; 120 micrograms for animals weighing 51 to 100 pounds; 180 micrograms for animals weighing over 100 pounds, German Shepherds, or German Shepherd mix.

(2) *Indications for use*. For the prevention of estrus (heat) in adult female dogs not intended primarily for breeding purposes.

(3) *Limitations*. Administer daily, orally or in a small amount of food, at least 30 days before expected initiation of heat, and continue daily as long as desired, but not for more than 24 months. Mibolerone should not be used in bitches before the first estrous period. It is not intended for animals being used primarily for breeding purposes. Use orally in adult female dogs only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 15625, Apr. 14, 1978]

§ 520.1445 Milbemycin oxime tablets.

(a) *Specifications*—(1) *Dogs*. Each tablet contains 2.3, 5.75, 11.5, or 23.0 milligrams of milbemycin oxime.

(2) *Cats*. Each tablet contains 5.75, 11.5, or 23.0 milligrams of milbemycin oxime.

(b) *Sponsor*. See 058198 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs and puppies*—(i) *Amount*. For hookworm, roundworm, and whipworm, use 0.23 milligram per pound of body weight (0.5 milligram per kilogram). For heartworm, use 0.05 milligram per pound of body weight (0.1 milligram per kilogram).

(ii) *Indications for use*. For prevention of heartworm disease caused by *Dirofilaria immitis*, control of hookworm infections caused by *Ancylostoma caninum*, and removal and control of adult roundworm infections caused by