

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

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at 4-day intervals of 2 milligrams per 2.2 pounds of body weight; not for use in laying chickens; chickens slaughtered 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 *Toxocara canis* and *Toxascaris leonina* and whipworm infections caused by *Trichuris vulpis* in dogs and in puppies 4 weeks of age or greater and 2 pounds of body weight or greater.

(iii) *Limitations.* Do not use in puppies less than 4 weeks of age and less than 2 pounds of body weight. Administer once a month. First dose given within 1 month after first exposure to mosquitoes and continue regular use until at least 1 month after end of mosquito season. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats and kittens—(i) Amount.* 0.91 milligram per pound of body weight (2.0 milligrams per kilogram).

(ii) *Indications for use.* For prevention of heartworm disease caused by *Dirofilaria immitis* and the removal of adult *Toxocara cati* (roundworm) and *Ancylostoma tubaeforme* (hookworm) infections in cats 6 weeks of age or greater and 1.5 pounds body weight or greater.

(iii) *Limitations.* Do not use in kittens less than 6 weeks of age or 1.5 pounds body weight. Administer once a month. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[55 FR 25301, June 21, 1990, as amended at 55 FR 49888, Dec. 3, 1990; 58 FR 5608, Jan. 22, 1993; 60 FR 50097, Sept. 28, 1995; 61 FR 43654, Aug. 26, 1996; 63 FR 29352, May 29, 1998; 63 FR 41189, Aug. 3, 1998]

§ 520.1446 Milbemycin oxime/lufenuron tablets.

(a) *Specifications.* Tablets containing: 2.3 milligrams milbemycin oxime/46 milligrams lufenuron, 5.75 milligrams/115 milligrams, 11.5 milligrams/230 milligrams, and 23 milligrams/460 milligrams.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use—(1) Dogs—(i) Amount.* 0.5 milligrams of milbemycin and 10 milligrams of lufenuron per kilogram of body weight.

(ii) *Indications for use.* For use in dogs and puppies for the prevention of heartworm disease caused by *Dirofilaria*