

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.* Each tablet contains 2.3, 5.75, 11.5, or 23.0 milligrams of milbemycin oxime.

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

(c) *Conditions of use—(1) Amount.* 0.23 milligram per pound of body weight (0.5 milligram per kilogram).

(2) *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.

(3) *Limitations.* Do not use in puppies less than 4 weeks of age and less than 2 pounds in 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.

[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]

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

(2) *Indications for use.* For use in dogs, 4 weeks of age and older and 2 pounds body weight or greater, for the prevention of heartworm disease caused by *Dirofilaria immitis*, for the prevention and control of flea populations, the control of adult *Ancylostoma caninum* (hookworm), and the removal and control of adult *Toxocara canis*, *Toxascaris leonina* (roundworm), and *Trichuris vulpis* (whipworm) infections.

(3) *Limitations.* Administer tablet(s) once a month, preferably on same date each time. All dogs in a household should be treated to achieve maximum efficacy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[62 FR 28629, May 27, 1997]

§ 520.1448 Monensin oral dosage forms.

Monensin, as the base or the sodium salt, contains a minimum of 90 percent monensin activity derived from monensin A and a minimum of 95 percent derived from monensin A plus B. Using thin layer chromatography, the R_f value must be comparable to a reference standard (the R_f value is the distance the spots travel from the starting line divided by the distance the solvent front travels from the starting line). The loss on drying is not more than 10 percent when dried in vacuum at 60 °C for 2 hours.

[55 FR 3586, Feb. 2, 1990]

§ 520.1448a Monensin blocks.

(a)(1) *Specifications.* Each pound of protein-mineral block contains 400 milligrams of monensin (0.088 percent) as monensin sodium.

(2) *Sponsor.* See 036904 in § 510.600(c) of this chapter.