

§ 520.1446

21 CFR Ch. I (4-1-10 Edition)

*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 and lufenuron tablets.**

(a) *Specifications—(1)* Tablets containing: 2.3 milligrams (mg) milbemycin oxime and 46 mg lufenuron, 5.75 mg milbemycin oxime and 115 mg lufenuron, 11.5 mg milbemycin oxime and 230 mg lufenuron, or 23 mg milbemycin oxime and 460 mg lufenuron.

(2) Flavored tablets containing: 2.3 mg milbemycin oxime and 46 mg lufenuron, 5.75 mg milbemycin oxime and 115 mg lufenuron, 11.5 mg milbemycin oxime and 230 mg lufenuron, or 23 mg milbemycin oxime and 460 mg lufenuron.

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

(c) [Reserved]

(d) *Conditions of use—(1) Dogs—(i) Amount.* 0.5 mg milbemycin oxime and 10 mg lufenuron per kilogram of body weight, once a month.

(ii) *Indications for use—(A)* For use in dogs and puppies for the prevention of heartworm disease caused by *Dirofilaria immitis*, for prevention and control of flea populations, for control of adult *Ancylostoma caninum* (hookworm), and for removal and control of adult *Toxocara canis*, *Toxascaris leonina* (roundworm), and *Trichuris vulpis* (whipworm) infections.

(B) The concurrent use of flavored milbemycin oxime and lufenuron tablets described in paragraph (a)(2) of this section as in paragraph (d)(1)(ii)(A) of this section with nitenpyram tablets as in § 520.1510(d)(1) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

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

(2) [Reserved]

[62 FR 28629, May 27, 1997, as amended at 63 FR 41190, Aug. 3, 1998; 68 FR 51905, Aug. 29, 2003]

§ 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<sub>f</sub>* value must be comparable to a reference standard (the *R<sub>f</sub>* 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 067949 in § 510.600(c) of this chapter.

(3) *Related tolerances.* See § 556.420 of this chapter.

(4) *Conditions of use*—(i) *Amount*. 80 to 200 milligrams of monensin (0.2 to 0.5 pound of block) per head per day.

(ii) *Indications for use*. Increased rate of weight gain.

(iii) *Limitations*. Block to be fed free choice to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers). Provide at least 1 block per 5 head of cattle. Feed blocks continuously. Do not feed salt or minerals containing salt. Do not allow horses or other equines access to formulations containing monensin (ingestion of monensin by equines has been fatal). The effectiveness of this block in cull cows and bulls has not been established.

(b) [Reserved]

(c)(1) *Specifications*. Each pound of protein block contains 175 milligrams of monensin (0.038 percent) as monensin sodium.

(2) *Sponsor*. See 021676 in § 510.600(c) of this chapter.

(3) *Related tolerances*. See § 556.420 of this chapter.

(4) *Conditions of use*—(i) *Amount*. 40 to 200 milligrams of monensin (0.25 to 1.13 pounds or 4 to 18 ounces of block) per head per day.

(ii) *Indications for use*. Increased rate of weight gain.

(iii) *Limitations*. Blocks to be fed free choice to pasture cattle (slaughter, stocker, and feeder). Provide at least 1 block per 4 head of cattle. Do not allow cattle access to salt or mineral while being fed this product. Ingestion by cattle of monensin at levels of 600 milligrams per head per day and higher has been fatal. Do not allow horses or other equines access to formulations containing monensin (ingestion of monensin by equines has been fatal). Block's effectiveness in cull cows and bulls has not been established.

(d)(1) *Specifications*. Each pound of block contains 400 milligrams of monensin (0.088 percent) as monensin sodium.

(2) *Sponsor*. See 051267 in § 510.600(c) of this chapter.

(3) *Related tolerances*. See § 556.420 of this chapter.

(4) *Conditions of use*—(i) *Amount*. 50 to 200 milligrams of monensin (2 to 8 ounces of block) per head per day.

(ii) *Indications for use*. Pasture cattle: Increased rate of weight gain.

(iii) *Limitations*. Blocks to be fed free choice to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers). Provide at least one block per five head of cattle. Feed blocks continuously. Do not feed salt or mineral supplements in addition to the blocks. Ingestion by cattle of monensin at levels of 600 milligrams per head per day and higher has been fatal. Do not allow horses or other equines access to formulations containing monensin (ingestion of monensin by equines has been fatal). The effectiveness of this block in cull cows and bulls has not been established.

[46 FR 19466, Mar. 31, 1981]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 520.1448a, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

#### § 520.1450 Morantel tartrate oral dosage forms.

##### § 520.1450a Morantel tartrate bolus.

(a) *Specifications*. Each bolus contains 2.2 grams morantel tartrate equivalent to 1.3 grams of morantel base.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.425 of this chapter.

(d) *Conditions of use*—(1) *Amount*. One bolus per 500 pounds of body weight (4.4 milligrams per pound of body weight) as a single oral dose. Boluses may be divided in half for more accurate dosing as follows: up to 325 pounds, ½ bolus; 326 to 600 pounds, 1 bolus; 601 to 900 pounds, 1½ boluses; and 901 to 1,200 pounds, 2 boluses.

(2) *Indications for use*. For removal and control of mature gastrointestinal nematode infections of cattle including stomach worms (*Haemonchus* spp., *Ostertagia* spp., *Trichostrongylus* spp.), worms of the small intestine (*Cooperia* spp., *Trichostrongylus* spp., *Nematodirus* spp.), and worms of the large intestine (*Oesophagostomum radiatum*).