Food and Drug Administration, HHS

§ 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.

(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 0.06 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...
§ 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)(i)(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]

§ 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.

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§ 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.