

§ 520.2380f

21 CFR Ch. I (4-1-11 Edition)

(c) *Conditions of use.* (1) Used for the treatment and control of bots (*Gasterophilus spp.*), large strongyles (*Strongylus spp.*), small strongyles (genera *Cyathostomum*, *Cylicobrachytus*, *Craterostomum*, *Oesophagodontus*, *Poteriostomum*), pinworms (*Oxyuris spp.*, *Strongyloides spp.*), and ascarids (*Parascaris spp.*) in horses.

(2) Administer 2 grams of thiabendazole with 1.8 grams of trichlorfon per 100 pounds of body weight sprinkled on the animals' usual daily ration of feed, or may be mixed in 5 to 10 fluid ounces of water and administered by stomach tube or drench.

(3) Do not re-treat more than once every 30 days, preferably every 6 to 8 weeks.

(4) Do not treat animals if sick or debilitated; less than 4 months of age; or mares in last month of pregnancy.

(5) Do not administer intravenous anesthetics, especially muscle relaxants, within 2 weeks of use.

(6) Not for animals intended for food use.

(7) Do not use within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(8) If the label bears directions for administration of the drug by stomach tube or drench it shall also bear the statement: Caution; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 23071, May 28, 1975, as amended at 48 FR 48229, Oct. 18, 1983]

§ 520.2380f Thiabendazole, piperazine phosphate powder.

(a) *Specifications.* Each ounce of water dispersible powder contains 6.67 grams of thiabendazole and 8.33 grams of piperazine (as piperazine phosphate).

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 2 grams of thiabendazole and 2.5 grams of piperazine (0.3 ounce of powder) per 100 pounds of body weight.

(2) *Indications for use.* Treatment of infections of large strongyles (genus *Strongylus*), small strongyles (genera *Cyathostomum*, *Cylicobrachytus*, and related genera *Craterostomum*, *Oesophagodontus*, *Poteriostomum*), pinworms (*Oxyuris*), threadworms

(*Strongyloides*), and ascarids (*Parascaris*) in horses.

(3) *Limitations.* Use a single oral dose. Administer as a drench or by stomach tube suspended in 1 pint of warm water; by dose syringe suspended in ½ ounce of water for each 100 pounds of body weight; or sprinkled over a small amount of daily feed. Not for animals intended for food use. If the label bears directions for administration by stomach tube or drench, it shall also bear the statement “Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian;” if not labeled for use by stomach tube or drench, the label shall bear the statement, “Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.”

[46 FR 18963, Mar 27, 1981, as amended at 46 FR 52330, Oct. 27, 1981; 62 FR 63271, Nov. 28, 1997]

§ 520.2455 Tiamulin.

(a) *Specifications.* (1) Each gram of soluble powder contains 450 milligrams (mg) tiamulin hydrogen fumarate.

(2) Each milliliter (mL) of solution contains 125 mg (12.5 percent) tiamulin hydrogen fumarate.

(3) Each mL of solution contains 123 mg (12.3 percent) tiamulin hydrogen fumarate.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 058198 for products described in paragraphs (a)(1) and (a)(2) of this section.

(2) No. 059130 for products described in paragraphs (a)(1) and (a)(3) of this section.

(c) *Related tolerances.* See § 556.738 of this chapter.

(d) *Conditions of use in swine*—(1) *Amounts and indications for use.* Administer in drinking water for 5 consecutive days:

(i) 3.5 mg per (l) lb of body weight daily for treatment of swine dysentery associated with *Brachyspira hyodysenteriae* susceptible to tiamulin.

(ii) 10.5 mg/lb of body weight daily for treatment of swine pneumonia due to *Actinobacillus pleuropneumoniae* susceptible to tiamulin.

(2) *Limitations.* Use as only source of drinking water. Prepare fresh medicated water daily. Withdraw medication 3 days before slaughter following treatment at 3.5 mg/lb and 7 days before slaughter following treatment at 10.5 mg/lb of body weight. Swine being treated with tiamulin should not have access to feeds containing polyether ionophores (e.g., lasalocid, monensin, narasin, salinomycin, or semduramycin) as adverse reactions may occur. The effects of tiamulin on swine reproductive performance, pregnancy, and lactation have not been determined.

[70 FR 75017, Dec. 19, 2005, as amended at 74 FR 7180, Feb. 13, 2009; 75 FR 54492, Sept. 8, 2010]

#### § 520.2473 Tioxidazole oral dosage forms.

##### § 520.2473a Tioxidazole granules.

(a) *Specifications.* Each gram of granules contains 200 milligrams of tioxidazole.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Horses—(i) Amount.* 5 milligrams per pound of body weight as a single dose.

(ii) *Indications for use.* Removal of mature large strongyles (*Strongylus edentatus*, *S. equinus*, and *S. vulgaris*), mature ascarids (*Parascaris equorum*), mature and immature (4th larval stage) pinworms (*Oxyuris equi*), and mature small strongyles (*Triodontophorus* spp.).

(iii) *Limitations.* For administration with feed: Sprinkle required amount of granules on a small amount of the usual grain ration and mix. Prepare for each horse individually. Withholding of feed or water not necessary. Not for use in horses intended for food. The reproductive safety of tioxidazole in breeding animals has not been determined. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. It is recommended that this drug be administered with caution to sick or debilitated horses.

(2) [Reserved]

[50 FR 52772, Dec. 26, 1985; 51 FR 2693, Jan. 21, 1986, as amended at 52 FR 7832, Mar. 13, 1987]

##### § 520.2473b Tioxidazole paste.

(a) *Specifications.* Each plastic syringe contains 6.25 grams of tioxidazole.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Horses—(i) Amount.* 5 milligrams of tioxidazole per pound of body weight as a single dose.

(ii) *Indications for use.* Removal of mature large strongyles (*Strongylus edentatus*, *S. equinus*, and *S. vulgaris*), mature ascarids (*Parascaris equorum*), mature and immature (4th larval stage) pinworms (*Oxyuris equi*), and mature small strongyles (*Triodontophorus* spp.).

(iii) *Limitations.* Administer orally by inserting the nozzle of the syringe through the space between front and back teeth and deposit the required dose on the base of the tongue. Before dosing, make sure the horse's mouth contains no feed. Not for use in horses intended for food. The reproductive safety of tioxidazole in breeding animals has not been determined. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. It is recommended that this drug be administered with caution to sick or debilitated horses.

(2) [Reserved]

[52 FR 43059, Nov. 9, 1987]

##### § 520.2475 Toceranib.

(a) *Specifications.* Each tablet contains 10, 15, or 50 milligrams (mg) toceranib as toceranib phosphate.

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

(c) *Conditions of use—(1) Dogs—(i) Amount.* Administer an initial dose of 3.25 mg per kilogram (1.48 mg per pound) body weight, orally every other day.

(ii) *Indications for use.* For the treatment of Patnaik grade II or III, recurrent, cutaneous mast cell tumors with or without regional lymph node involvement.

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

(2) [Reserved]

[74 FR 28875, June 18, 2009]