

§ 520.2455

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. 066104 for the product described in paragraph (a)(1) of this section.

(3) No. 000859 for the product described in paragraph (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 (✓) 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

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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; 77 FR 56770, Sept. 14, 2012; 78 FR 17596, Mar. 22, 2013]

§ 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]

§ 520.2483 Triamcinolone.

(a) *Specifications*.—(1) Each tablet contains 0.5 milligram (mg) or 1.5 mg triamcinolone acetonide.

(2) Each 15 grams of powder contains 10 mg triamcinolone acetonide.

(b) *Sponsor*. See No. 000010 in § 510.600(c) of this chapter.

(c) *Special considerations*. See § 510.410 of this chapter.

(d) *Conditions of use*—(1) *Dogs and cats*. Use tablets described in paragraph (a)(1) of this section as follows:

(i) *Amount*. Administer 0.05 mg per pound (lb) of body weight daily by mouth; up to 0.1 mg per pound (lb) of body weight daily, if response to the smaller dose is inadequate. Therapy may be initiated with a single injection of triamcinolone acetonide suspension as in § 522.2483 of this chapter, in which case triamcinolone acetonide tablets should be administered beginning 5 to 7 days after the injection.

(ii) *Indications for use*. As an anti-inflammatory agent.

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

(2) *Horses*. Use oral powder described in paragraph (a)(2) of this section as follows:

(i) *Amount*. Administer 0.005 to 0.01 mg/lb of body weight twice daily, sprinkled (top-dressed) on a small portion of feed. Therapy may be initiated with a single injection of triamcinolone acetonide suspension as in § 522.2483 of this chapter, in which case triamcinolone acetonide oral powder should be administered beginning 3 or 4 days after the injection.

(ii) *Indications for use*. As an anti-inflammatory agent.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Do not use in horses intended for human consumption.

[75 FR 10166, Mar. 5, 2010]

§ 520.2520 Trichlorfon oral dosage forms.

§ 520.2520b Trichlorfon and atropine.

(a) *Chemical name*. (1) For trichlorfon: *O,O*-Dimethyl 2,2,2-trichloro-1-hydroxyethyl phosphonate.

(2) For atropine: Atropine N.F.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is used for the treatment of *Syphacia obvelata* (pinworm) in laboratory mice.