

§ 520.2611

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Animal body weight (pounds)	Number of tablets
30 MG TABLETS	
2.2 .....	1
4.4 .....	2
6.6 .....	3
8.8 .....	4
120 MG TABLETS	
Up to 9 .....	1
10 to 19 .....	2
20 to 29 .....	3
30 to 40 .....	4
480 MG TABLETS	
30 to 40 .....	1
40 to 60 .....	1½
60 to 80 .....	2
80 to 110 .....	3
Over 110 .....	4

(3) The drug is given once daily. Alternatively, especially in severe infections, the initial dose may be followed by one-half the recommended daily dose every 12 hours. If no improvement is seen in 3 days, discontinue therapy and reevaluate diagnosis.

(4) Administer for 2 to 3 days after symptoms have subsided. Do not treat for more than 14 consecutive days.

(5) During long term treatment, periodic platelet counts and white and red blood cell counts are recommended.

(6) The drug should not be used in patients showing marked liver parenchymal damage or blood dyscrasia, nor in those with a history of sulfonamide sensitivity.

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

[41 FR 3853, Jan. 27, 1976, as amended at 44 FR 32214, June 5, 1979; 46 FR 23231, Apr. 24, 1981; 47 FR 36814, Aug. 24, 1982; 50 FR 9800, Mar. 12, 1985; 50 FR 11852, Mar. 26, 1985; 61 FR 5506, Feb. 13, 1996; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 520.2611 Trimethoprim and sulfadiazine paste.

(a) *Specifications.* Each gram (g) of paste contains 67 milligrams (mg) trimethoprim and 333 mg sulfadiazine.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter:

(1) No. 000856 for product administered as in paragraph (c)(1)(i) of this section.

(2) No. 000061 for product administered as in paragraph (c)(1)(ii) of this section.

(c) *Conditions of use in horses*—(1) *Amount.* Administer orally as a single daily dose for 5 to 7 days:

(i) 5 g of paste (335 mg trimethoprim and 1,665 mg sulfadiazine) per 150 pounds (68 kilograms) of body weight per day.

(ii) 3.75 g of paste (250 mg trimethoprim and 1,250 mg sulfadiazine) per 110 pounds (50 kilograms) of body weight per day.

(2) *Indications for use.* For use where systemic antibacterial action against sensitive organisms is required during treatment of acute strangles, respiratory infections, acute urogenital infections, and wound infections and abscesses.

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

[71 FR 30802, May 31, 2006]

§ 520.2612 Trimethoprim and sulfadiazine suspension.

(a) *Specifications.* Each milliliter (mL) of suspension contains:

(1) 10 milligrams (mg) trimethoprim and 50 mg sulfadiazine; or

(2) 400 mg combined active ingredients (67 mg trimethoprim and 333 mg sulfadiazine).

(b) *Sponsors.* See sponsor numbers in § 510.600 of this chapter:

(1) No. 000061 for use of product described in paragraph (a)(1) for use as in paragraph (c)(1) of this section.

(2) No. 051072 for use of product described in paragraph (a)(2) for use as in paragraph (c)(2) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 1 mL (10 mg trimethoprim and 50 mg sulfadiazine) per 5 pounds (lb) of body weight once daily, or one-half the recommended daily dose every 12 hours, for up to 14 consecutive days.

(ii) *Indications for use.* The drug is used in dogs where systemic antibacterial action against sensitive organisms is required, either alone or as an adjunct to surgery or debridement with associated infection. The drug is indicated where control of bacterial infection is required during the treatment

of acute urinary tract infections, acute bacterial complications of distemper, acute respiratory tract infections, acute alimentary tract infections, wound infections, and abscesses.

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

(2) *Horses*—(i) *Amount.* Administer 24 mg combined active ingredients per kilogram of body weight (2.7 mL/100 lb) twice daily for 10 days.

(ii) *Indications for use.* For the treatment of lower respiratory tract infections in horses caused by susceptible strains of *Streptococcus equi* subsp. *zooepidemicus*.

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

[78 FR 63872, Oct. 25, 2013]

#### § 520.2613 Trimethoprim and sulfadiazine powder.

(a) *Specifications.* Each gram of powder contains 67 milligrams of trimethoprim and 333 milligrams of sulfadiazine.

(b) *Sponsor.* See No. 000009 and 058711 in § 510.600(c) of this chapter.

(c) *Conditions of use: Horses*—(1) *Dosage.* 3.75 grams of powder per 110 pounds (50 kilograms) of body weight per day.

(2) *Indications for use.* For control of bacterial infections of horses during treatment of acute strangles, respiratory tract infections, acute urogenital infections, wound infections, and abscesses.

(3) *Limitations.* Administer orally in a small amount of feed, as a single daily dose, for 5 to 7 days. Continue therapy for 2 to 3 days after clinical signs have subsided. If no improvement is seen in 3 to 5 days, reevaluate diagnosis. A complete blood count should be done periodically with prolonged use. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 36135, July 6, 1993, as amended at 64 FR 68289, Dec. 7, 1999]

#### § 520.2640 Tylosin.

(a) *Specifications.* Each container of soluble powder contains tylosin tar-

trate equivalent to either 100 or 256 grams tylosin base.

(b) *Sponsors.* See Nos. 000986, 016592, and 061623 in § 510.600(c) of this chapter.

(1) No. 000986 for use of a 100-gram jar as in paragraph (d) of this section.

(2) No. 016592 for use of a 100-gram jar or pouch as in paragraphs (d)(1), (d)(2), (d)(3)(i), (d)(3)(ii)(B), (d)(3)(iii), and (d)(4) of this section.

(3) No. 061623 for use of a 100- or 256-gram jar or pouch as in paragraphs (d)(1), (d)(2), (d)(3)(i), (d)(3)(ii)(B), (d)(3)(iii), and (d)(4) of this section.

(c) *Related tolerances.* See § 556.740 of this chapter.

(d) *Conditions of use*—(1) *Chickens*—(i) *Amount.* 2 grams per gallon for 1 to 5 days as the sole source of drinking water. Treated chickens should consume enough medicated drinking water to provide 50 milligrams (mg) tylosin per pound of body weight per day.

(ii) *Indications for use.* For maintaining weight gain and feed efficiency in the presence of infectious sinusitis associated with *Mycoplasma gallisepticum* sensitive to tylosin.

(iii) *Limitations.* Prepare a fresh solution every 3 days. Do not use in layers producing eggs for human consumption. Do not administer within 24 hours of slaughter.

(2) *Turkeys*—(i) *Amount.* 2 grams per gallon for 2 to 5 days as the sole source of drinking water. Treated turkeys should consume enough medicated drinking water to provide 60 mg tylosin per pound of body weight per day.

(ii) *Indications for use.* For maintaining weight gains and feed efficiency in the presence of infectious sinusitis associated with *Mycoplasma gallisepticum* sensitive to tylosin.

(iii) *Limitations.* Prepare a fresh solution every 3 days. Do not use in layers producing eggs for human consumption. Do not administer within 5 days of slaughter.

(3) *Swine*—(i) *Amount.* 250 mg per gallon as the only source of drinking water for 3 to 10 days, depending on the severity of the condition being treated.

(ii) *Indications for use.* (A) For the treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae* when followed immediately by tylosin phosphate medicated