Food and Drug Administration, HHS

§ 520.2612 Trimethoprim and sulfadiazine oral suspension.

(a) Specifications. Each milliliter of oral suspension contains 60 milligrams of drug (10 milligrams of trimethoprim and 50 milligrams of sulfadiazine).

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

(c) Conditions of use. Dogs—(1) Dosage. 1 milliliter (10 milligrams of

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.


§ 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]
$\S\ 520.2613$  
trimethoprim and 50 milligrams of sulfadiazine) per 5 pounds of body weight.

(2) **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.

(3) **Limitations.** For oral use only. Administer the recommended dose once daily or one-half the recommended daily dose every 12 hours. Administer for 2 to 3 days after symptoms have subsided. If no improvement is seen in 3 days, discontinue therapy and re-evaluate diagnosis. Do not treat for more than 14 consecutive days. During long-term treatment, a complete blood count is recommended. 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. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


$\S\ 520.2613$ **Trimethoprim and sulfadiazine powder.**

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

(b) **Sponsor.** See No. 000096 and 016592 in §510.600(c) of this chapter.

(c) **Conditions of use: Horses—**

(i) **Dosage.** 3.75 grams of powder per 110 pounds (50 kilograms) of body weight per day.

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

(iii) **Limitations.** Administer orally in a small amount of feed, as a single daily dose, for 3 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 66268, Dec. 7, 1999]

$\S\ 520.2640$ **Tylosin.**

(a) **Specifications.** Each container of soluble powder contains tylosin tartrate 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 24 hours of slaughter.