

pound of body weight daily. It is administered to cats intramuscularly at a dosage level of 2 to 4 milligrams per pound of body weight daily. It is administered to horses intravenously or intramuscularly at a dosage level of 10 to 15 milligrams per 100 pounds of body weight daily to a maximum dose of 100 milligrams.¹

(3) Not for use in horses intended for food.¹

(4) Do not use in conjunction with organophosphates and/or procaine hydrochloride, because phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.¹

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13858, Mar. 27, 1975, as amended at 50 FR 41490, Oct. 11, 1985]

§ 522.2610 Trimethoprim and sulfadiazine sterile suspension.

(a)(1) *Specifications.* Each milliliter of sterile aqueous suspension contains 240 milligrams (40 milligrams of trimethoprim and 200 milligrams of sulfadiazine).

(2) *Sponsor.* See 000061 and 000856 in § 510.600(c) of this chapter.

(3) *Conditions of use—(i) Dosage.* One milliliter (40 milligrams of trimethoprim and 200 milligrams of sulfadiazine) per 20 pounds (9 kilograms) of body weight per day.

(ii) *Indications.* For dogs for treatment of acute urinary tract infections, acute bacterial complications of distemper, acute respiratory tract infections, acute alimentary tract infections, and acute septicemia due to *Streptococcus zooepidemicus*.

(iii) *Limitations.* For subcutaneous use in dogs only; administer once every 24 hours, or for severe infections, after an initial dose, administer half the normal daily dose every 12 hours; continue therapy 2 to 3 days after clinical signs of infection have subsided; if no improvement is seen in 3 to 5 days, re-

¹These conditions are NAS/NRC reviewed and are deemed effective. Applications for these uses need not include the effectiveness data specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

evaluate diagnosis; injection may be used alone or in conjunction with oral dosing; not recommended for use for more than 14 days; a complete blood count should be done for prolonged use; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications.* Each milliliter of sterile aqueous suspension contains 480 milligrams (80 milligrams of trimethoprim and 400 milligrams of sulfadiazine (as the sodium salt)).

(2) *Sponsor.* See 000856 and 011716 in § 510.600(c) of this chapter.

(3) *Conditions of use—(i) Dosage.* Two milliliters (160 milligrams of trimethoprim and 800 milligrams of sulfadiazine) per 100 pounds (45 kilograms) of body weight per day.

(ii) *Indications.* For horses where systemic anti-bacterial action against sensitive organisms is required during treatment of acute strangles, respiratory tract infections, acute urogenital infections, and wound infections and abscesses.

(iii) *Limitations.* For intravenous use; administer as single, daily dose for 5 to 7 days; daily dose may also be halved and given morning and evening; continue acute infection therapy 2 to 3 days after clinical signs have subsided; if no improvement of acute infections is seen in 3 to 5 days, reevaluate diagnosis; a complete blood count should be done periodically for 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.

[48 FR 241, Jan. 4, 1983, as amended at 48 FR 23180, May 24, 1983; 48 FR 42809, Sept. 20, 1983; 61 FR 5507, Feb. 13, 1996; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 522.2615 Tripeleppamine hydrochloride injection.

(a) *Specifications.* Each milliliter of aqueous solution contains 20 milligrams of tripeleppamine hydrochloride.

(b) *Sponsor.* See Nos. 053501 and 059130 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.741 of this chapter.

(d) *Conditions of use—(1) Amount—(i) Dogs, cats, and horses.* For intramuscular use only at a dose of 0.5 milligram per pound of body weight.

(ii) *Cattle*. Administer intravenously or intramuscularly at a dose of 0.5 milligram per pound of body weight.

(2) *Indications for use*. For use in treating conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease.

(3) *Limitations*. Do not use in horses intended for food purposes. Treated cattle must not be slaughtered for food during treatment and for 4 days following the last treatment. Milk that has been taken during treatment and for 24 hours (two milkings) after the last treatment must not be used for food. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[51 FR 44450, Dec. 10, 1986, as amended at 61 FR 29480, June 11, 1996; 62 FR 4164, Jan. 29, 1997]

§ 522.2640 Tylosin injectable dosage forms.

§ 522.2640a Tylosin injection.

(a) *Specifications*. Each milliliter of sterile solution of 50 percent propylene glycol with 4 percent benzyl alcohol contains 50 to 200 milligrams of tylosin activity (as tylosin base). Tylosin conforms to the appropriate antibiotic standard. Tylosin contains at least 95 percent tylosin as a combination of tylosin A, tylosin B, tylosin C, and tylosin D of which at least 80 percent is tylosin A as determined by a method entitled "Determination of Factor Content in Tylosin by High Performance Liquid Chromatography," which is incorporated by reference. Copies are available from the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20001.

(b) *Sponsors*. (1) See No. 000986 in § 510.600(c) of this chapter for use in paragraphs (e)(1), (2), and (3) of this section.

(2) See No. 000010 in § 510.600(c) of this chapter for use as in paragraphs (e)(1) and (2) of this section.

(c) *NAS/NRC status*. These conditions of use are NAS/NRC reviewed and found effective. NADA's for these uses need not include effectiveness data as specified by § 514.111 of this chapter but may require bioequivalency and safety information.

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

(e) *Conditions of use*—(1) *Beef cattle and nonlactating dairy cattle*—(i) *Amount*. 8 milligrams per pound of body weight once daily.

(ii) *Indications for use*. Treatment of bovine respiratory complex (shipping fever, pneumonia) usually associated with *Pasteurella multocida* and *Corynebacterium pyogenes*; foot rot (necrotic pododermatitis) and calf diphtheria caused by *Fusobacterium necrophorum* and metritis caused by *Corynebacterium pyogenes*.

(iii) *Limitations*. Administer intramuscularly for not more than 5 consecutive days. Continue treatment 24 hours after symptoms disappear. Do not inject more than 10 milliliters per site. Do not use in lactating dairy cattle. Use a 50-milligram-per-milliliter solution for calves weighing less than 200 pounds. Do not administer within 21 days of slaughter.

(2) *Swine*—(i) *Amount*. 4 milligrams per pound of body weight twice daily.

(ii) *Indications for use*. Treatment of swine arthritis caused by *Mycoplasma hyosynoviae*; swine pneumonia caused by *Pasteurella* spp.; swine erysipelas caused by *Erysipelothrix rhusiopathiae*; swine dysentery associated with *Treponema hyodysenteriae* when followed by appropriate medication in the drinking water and/or feed.

(iii) *Limitations*. Administer intramuscularly for not more than 3 consecutive days. Continue treatment 24 hours after symptoms disappear. Do not inject more than 5 milliliters per site. Do not administer within 14 days of slaughter. If tylosin medicated drinking water is used as followup treatment for swine dysentery, the animal should thereafter receive feed containing 40 to 100 grams of tylosin per ton for 2 weeks to assure depletion of tissue residues.