

§522.2610

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anxiety and to help control psychomotor overactivity as well as to increase the tolerance of animals to pain and pruritus. The drug is indicated in various office and clinical procedures which require the aid of a tranquilizer, antiemetic, or preanesthetic.<sup>1</sup>

(2) The drug is administered to dogs either intravenously at a dosage level of 0.5 to 1 milligram per pound of body weight daily, or intramuscularly at a dosage level of 1 to 2 milligrams per 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.<sup>1</sup>

(3) Not for use in horses intended for food.<sup>1</sup>

(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.<sup>1</sup>

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

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

§522.2610 Trimethoprim and sulfadiazine.

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

(1) 40 milligrams (mg) trimethoprim suspended in a solution containing 200 mg sulfadiazine; or

(2) 80 mg trimethoprim suspended in a solution containing 400 mg sulfadiazine (as the sodium salt).

(b) *Sponsors.* See Nos. 000061 and 000856 in §510.600(c) of this chapter.

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

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 1 mL of the product described

in paragraph (a)(1) of this section (40 mg trimethoprim and 200 mg sulfadiazine) per 20 pounds (9 kilograms) of body weight per day by subcutaneous injection.

(ii) *Indications for use.* For the 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*.

(2) *Horses*—(i) *Amount.* 2 mL of the product described in paragraph (a)(2) of this section (160 mg trimethoprim and 800 mg sulfadiazine) per 100 pounds (45 kilograms) of body weight per day by intravenous injection as single, daily dose for 5 to 7 days. The daily dose may also be halved and given morning and evening.

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

(iii) *Limitations.* Not for use in horses intended for human consumption.

[71 FR 30803, May 31, 2006]

§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

<sup>1</sup>These 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.

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]

#### § 522.2630 Tulathromycin.

(a) *Specifications.* Each milliliter of solution contains 100 milligrams (mg) tulathromycin.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.745 of this chapter.

(d) *Conditions of use*—(1) *Beef and non-lactating dairy cattle*—(i) *Amount.* 2.5 mg per kilogram (/kg) body weight as a single subcutaneous injection in the neck.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*. For the control of respiratory disease in cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, *H. somni*, and *M. bovis*. For the treatment of infectious bovine keratoconjunctivitis associated with *Moraxella bovis*. For the treatment of bovine foot rot (interdigital necrobacillosis) associated with *Fusobacterium necrophorum* and *Porphyromonas levii*.

(iii) *Limitations.* Cattle intended for human consumption must not be slaughtered within 18 days from the last treatment. Do not use in female dairy cattle 20 months of age or older. 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.

(2) *Swine*—(i) *Amount.* 2.5 mg/kg body weight as a single intramuscular injection in the neck.

(ii) *Indications for use.* For the treatment of swine respiratory disease (SRD) associated with *Actinobacillus*

*pleuropneumoniae*, *P. multocida*, *Bordetella bronchiseptica*, *Haemophilus parasuis*, and *Mycoplasma hyopneumoniae*; and for the control of SRD associated with *A. pleuropneumoniae*, *P. multocida*, and *M. hyopneumoniae* in groups of pigs where SRD has been diagnosed.

(iii) *Limitations.* Swine intended for human consumption must not be slaughtered within 5 days from the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[70 FR 39918, July 12, 2005, as amended at 71 FR 57416, Sept. 29, 2006; 72 FR 54540, Sept. 26, 2007; 73 FR 6018, Feb. 1, 2008; 73 FR 58872, Oct. 8, 2008; 74 FR 53165, Oct. 16, 2009]

#### § 522.2640 Tylosin.

(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 Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(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) [Reserved]

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

(e) *Conditions of use*—(1) *Beef cattle and nonlactating dairy cattle*—(i)