

§ 522.2471

21 CFR Ch. I (4–1–10 Edition)

duration (30 minutes) requiring mild to moderate analgesia.

(2) *Amount*. Expressed as milligrams of the drug combination:

(i) In healthy dogs: An initial intramuscular dosage of 3 to 4.5 milligrams per pound of body weight for diagnostic purposes; 4.5 to 6 milligrams per pound of body weight for minor procedures of short duration such as repair of lacerations and wounds, castrations, and other procedures requiring mild to moderate analgesia. Supplemental doses when required should be less than the initial dose and the total dose given should not exceed 12 milligrams per pound of body weight. The maximum total safe dose is 13.6 milligrams per pound of body weight.

(ii) In healthy cats: An initial intramuscular dosage of 4.4 to 5.4 milligrams per pound of body weight is recommended for such procedures as dentistry, treatment of abscesses, foreign body removal, and related types of surgery; 4.8 to 5.7 milligrams per pound of body weight for minor procedures requiring mild to moderate analgesia, such as repair of lacerations, castrations, and other procedures of short duration. Initial dosages of 6.5 to 7.2 milligrams per pound of body weight are recommended for ovariectomy and onychectomy. When supplemental doses are required, such individual supplemental doses should be given in increments that are less than the initial dose and the total dose given (initial dose plus supplemental doses) should not exceed the maximum allowable safe dose of 32.7 milligrams per pound of body weight.

(3) *Limitations*. Discard unused reconstituted solution after 48 hours. Not for use in dogs and cats with pancreatic disease, or with severe cardiac or pulmonary dysfunction. Not for use in pregnant animals. Not for use in cats suffering with renal insufficiency. The dosage should be reduced in geriatric dogs and cats. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 15328, Apr. 9, 1982, as amended at 51 FR 24142, July 2, 1986; 67 FR 67521, Nov. 6, 2002]

§ 522.2471 **Tilmicosin.**

(a) *Specifications*. Each milliliter of solution contains 300 milligrams (mg) tilmicosin base as tilmicosin phosphate.

(b) *Sponsor*. See No. 000986 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.735 of this chapter.

(d) *Special considerations*. (1) Not for human use. Use of this antibiotic in humans may prove fatal. Do not use in automatically powered syringes.

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

(e) *Conditions of use*—(1) *Cattle*—(i) *Amount*. 10 to 20 milligrams per kilogram (mg/kg) of body weight as a single subcutaneous injection.

(ii) *Indications for use*. For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*. For the control of respiratory disease in cattle at high risk of developing BRD associated with *M. haemolytica*.

(iii) *Limitations*. Do not use in female dairy cattle 20 months of age or older. Use of this antibiotic in this class of cattle may cause milk residues. Do not slaughter within 42 days of last treatment.

(2) *Sheep*—(i) *Amount*. 10 mg/kg body weight as a single subcutaneous injection.

(ii) *Indications for use*. For the treatment of ovine respiratory disease (ORD) associated with *Mannheimia (P.) haemolytica*.

(iii) *Limitations*. Do not slaughter within 28 days of last treatment.

[67 FR 72367, Dec. 5, 2002, as amended at 75 FR 9334, Mar. 2, 2010]

§ 522.2474 **Tolazoline hydrochloride injection.**

(a) *Specifications*. Each milliliter of sterile aqueous solution contains tolazoline hydrochloride equivalent to 100 milligrams of base activity.

(b) *Sponsor*. See No. 061690 in § 510.600(c) of this chapter.

(c) *Conditions of use*. It is used as follows:

(1) *Horses*—(i) *Amount*. Administer slowly by intravenous injection 4 milligrams per kilogram of body weight or