

§ 520.447

21 CFR Ch. I (4–1–02 Edition)

§ 520.447 **Clindamycin hydrochloride liquid.**

(a) *Specifications.* Each milliliter of 8.64 percent alcoholic solution contains the equivalent of 25 milligrams of clindamycin (as the hydrochloride).

(b) *Sponsor.* See Nos. 000009 and 059130 in § 510.600(c) of this chapter for use as in paragraphs (c) and (d) of this section.

(c) *Conditions of use in dogs*—(1) *Amount.* Wounds, abscesses, and dental infections: 2.5 milligrams per pound of body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 milligrams per pound of body weight every 12 hours for a minimum of 28 days.

(2) *Indications for use.* For use in dogs for treatment of soft tissue infections (wounds and abscesses), dental infections, and osteomyelitis caused by susceptible strains of *Staphylococcus aureus* and for soft tissue infections (deep wounds and abscesses), dental infections, and osteomyelitis caused by or associated with susceptible strains of *Bacteroides fragilis*, *Bacteroides melaninogenicus*, *Fusobacterium necrophorum*, and *Clostridium perfringens*.

(3) *Limitations.* Wound infections, abscesses, and dental infections: Do not use for more than 4 days if no improvement of acute infection is observed. Osteomyelitis: Do not use for more than 28 consecutive days if no improvement is observed. Because of potential adverse gastrointestinal effects, do not administer to rabbits, hamsters, guinea pigs, horses, chinchillas, or ruminating animals. Use with caution in animals receiving neuromuscular blocking agents, because clindamycin may potentiate their action. Prescribe with caution in atopic animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use in cats*—(1) *Amount.* 5.0 to 10.0 milligrams per pound of body weight every 24 hours for a maximum of 14 days (11 to 22 milligrams per kilogram of body weight per day).

(2) *Indications for use.* Aerobic bacteria: Treatment of soft tissue infections (wounds and abscesses) and dental infections caused by or associated with susceptible strains of *Staphy-*

lococcus aureus, *S. intermedius*, and *Streptococcus spp.* Anaerobic bacteria: Treatment of soft tissue infections (deep wounds and abscesses) and dental infections caused by or associated with susceptible strains of *Clostridium perfringens* and *Bacteroides fragilis*.

(3) *Limitations.* Wound infections, abscesses, and dental infections: Do not use for more than 4 days if no improvement of acute infection is observed. Because of potential adverse gastrointestinal effects, do not administer to rabbits, hamsters, guinea pigs, horses, chinchillas, or ruminating animals. Use with caution in animals receiving neuromuscular blocking agents, because clindamycin may potentiate their action. Prescribe with caution in atopic animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[50 FR 21239, May 23, 1985, as amended at 51 FR 34960, Oct. 1, 1986; 54 FR 47766, Nov. 17, 1989; 61 FR 59003, Nov. 20, 1996; 62 FR 46669, Sept. 4, 1997; 66 FR 13848, Mar. 8, 2001]

§ 520.452 **Clenbuterol syrup.**

(a) *Specifications.* Each milliliter contains 72.5 micrograms of clenbuterol hydrochloride.

(b) *Sponsor.* See 000010 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Horses*—(i) *Amount.* Administer orally twice a day (b.i.d.). Initial dose is 0.5 milliliter per 100 pounds body weight (0.8 micrograms per kilogram) for 3 days (6 treatments). If no improvement, administer 1 milliliter per 100 pounds (1.6 micrograms per kilogram) for 3 days (6 treatments). If no improvement, administer 1.5 milliliters per 100 pounds (2.4 micrograms per kilogram) for 3 days (6 treatments). If no improvement, administer 2.0 milliliters per 100 pounds (3.2 micrograms per kilogram) for 3 days (6 treatments). If no improvement, horse is non-responder to clenbuterol and treatment should be discontinued.

(ii) *Indications for use.* Indicated for the management of horses affected with airway obstruction, such as occurs in chronic obstructive pulmonary disease (COPD).

(iii) *Limitations.* Treat at effective dose for 30 days. At the end of the 30-day treatment period, drug should be

withdrawn. If signs return, the 30-day treatment period may be repeated. If repeating treatment, the step-wise dosage schedule should be repeated. The effect of this drug on breeding stallions and brood mares has not been determined. Treatment starting with dosages higher than the initial dose is not recommended. Federal law prohibits the extralabel use of this drug in food animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 41419, Aug. 4, 1998]

§ 520.455 Clomipramine hydrochloride tablets.

(a) *Specifications.* Each tablet contains 20, 40, or 80 milligrams of clomipramine hydrochloride.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* 2 to 4 milligrams of clomipramine hydrochloride per kilogram (0.9 to 1.8 milligrams per pound) of body weight per day, administered as a single daily dose or divided twice daily.

(2) *Indications for use.* For use as part of a comprehensive behavioral management program to treat separation anxiety in dogs greater than 6 months of age.

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

[64 FR 1762, Jan. 12, 1999]

§ 520.462 Clorsulon drench.

(a) *Specifications.* The drug is a suspension containing 8.5 percent clorsulon (85 milligrams per milliliter).

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use. Cattle—(1) Amount.* One-quarter fluid ounce per 200 pounds of body weight (7 milligrams per kilogram or 3.2 milligrams per pound of body weight).

(2) *Indications for use.* For the treatment of immature and adult liver fluke (*Fasciola hepatica*) infestations in cattle.

(3) *Limitations.* Using dose syringe, deposit drench over back of tongue. Do not treat cattle within 8 days of slaughter. Because a withdrawal time

in milk has not been established, do not use in female dairy cattle of breeding age. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[50 FR 10221, Mar. 14, 1985, as amended at 62 FR 63270, Nov. 28, 1997]

§ 520.530 Cythioate oral liquid.

(a) *Specifications.* Each milliliter contains 15 milligrams of cythioate.

(b) *Sponsor.* See Nos. 000859 and 010042 in § 510.600 of this chapter.

(c) *Special considerations.* Cythioate is a cholinesterase inhibitor. Do not use this product in animals simultaneously with or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, insecticides, pesticides, or chemicals.

(d) *Conditions of use—(1) Amount.* 15 milligrams cythioate per 10 pounds of body weight every third day or twice a week.

(2) *Indications for use.* Dogs, for control of fleas.

(3) *Limitations.* For oral use in dogs only. Do not use in greyhounds or in animals that are pregnant, sick, under stress, or recovering from surgery. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[49 FR 5614, Feb. 14, 1984]

§ 520.531 Cythioate tablets.

(a) [Reserved]

(b) *Sponsors.* See No. 000859 in § 510.600(c) of this chapter for use of 30- and 90-milligram (mg) tablets and see No. 010042 in § 510.600(c) of this chapter for use of 30-mg tablet.

(c) *Special considerations.* Cythioate is a cholinesterase inhibitor. Do not use this product in animals simultaneously with or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, insecticides, pesticides, or chemicals.

(d) *Conditions of use—(1) Amount.* 30 milligrams cythioate per 20 pounds of body weight every third day or twice a week.

(2) *Indications for use.* Dogs, for control of fleas.

(3) *Limitations.* For oral use in dogs only. Do not use in greyhounds or in animals that are pregnant, sick, under