

§ 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