

§ 520.88g Amoxicillin trihydrate and clavulanate potassium film-coated tablets.

(a) *Specifications.* Each tablet contains amoxicillin trihydrate and clavulanate potassium, equivalent to either 50 milligrams of amoxicillin and 12.5 milligrams clavulanic acid, or 100 milligrams of amoxicillin and 25 milligrams clavulanic acid, or 200 milligrams amoxicillin and 50 milligrams clavulanic acid or 300 milligrams amoxicillin and 75 milligrams clavulanic acid.

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

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 6.25 milligrams (equivalent to 5 milligrams amoxicillin and 1.25 milligrams clavulanic acid) per pound of body weight twice daily.

(ii) *Indications for use.* Treatment of skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of beta-lactamase (penicillinase) *Staphylococcus aureus*, nonbeta-lactamase *S. aureus*, *Staphylococcus* spp., *Streptococcus* spp., and *Escherichia coli*. Treatment of periodontal infections due to susceptible strains of aerobic and anaerobic bacteria.

(iii) *Limitations.* Wounds, abscesses, cellulitis, and superficial/juvenile pyoderma: Treat for 5 to 7 days or for 48 hours after all signs have subsided. If no improvement is seen after 5 days of treatment, discontinue therapy and reevaluate diagnosis. Deep pyoderma may require treatment for 21 days; do not treat for more than 30 days. Not for use in dogs maintained for breeding. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* 62.5 milligrams (1 milliliter) (50 milligrams amoxicillin and 12.5 milligrams clavulanic acid) twice daily.

(ii) *Indications for use.* Treatment of skin and soft tissue infections, such as wounds, abscesses and cellulitis/dermatitis due to susceptible strains of beta-lactamase (penicillinase) producing *S. aureus*, nonbeta-lactamase producing *S. aureus*, *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *Pasteurella* spp. Also, treatment of urinary tract infec-

tions (cystitis) due to susceptible strains of *E. coli*.

(iii) *Limitations.* Skin and soft tissue infections: abscesses, cellulitis/dermatitis should be treated for 5 to 7 days or for 48 hours after all signs have subsided. If no response is seen after 3 days of treatment, therapy should be discontinued and diagnosis reevaluated. Urinary tract infections may require treatment for 10 to 14 days or longer. The maximum duration of treatment should not exceed 30 days. Safety of use in pregnant or breeding animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37320, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995; 63 FR 13121, Mar. 18, 1998]

§ 520.88h Amoxicillin trihydrate and clavulanate potassium for oral suspension.

(a) *Specifications.* When reconstituted, each milliliter contains amoxicillin trihydrate equivalent to 50 milligrams of amoxicillin with clavulanate potassium equivalent to 12.5 milligrams of clavulanic acid.

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

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 6.25 milligrams (equivalent to 5 milligrams amoxicillin and 1.25 milligrams clavulanic acid) per pound of body weight twice daily.

(ii) *Indications for use.* Treatment of skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of beta-lactamase (penicillinase) producing *Staphylococcus aureus*, nonbeta-lactamase *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., and *Escherichia coli*. Treatment of periodontal infections due to susceptible strains of aerobic and anaerobic bacteria.

(iii) *Limitations.* Administer for 5 to 7 days or 48 hours after all symptoms subsided. Deep pyoderma may require 21 days, not to exceed 30 days. If no improvement is seen in 5 days, discontinue therapy and reevaluate the case. Not for use in dogs maintained for breeding. Federal law restricts this