$520.82 Aminopropazine fumarate oral dosage forms.

$520.82a Aminopropazine fumarate tablets.

(a) Specifications. The drug is in tablet form. Each tablet contains aminopropazine fumarate equivalent to 25 milligrams of aminopropazine base.

(b) Sponsor. See No. 000661 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is used in dogs and cats for reducing excessive smooth muscle contractions, such as occur in urethral spasms associated with urolithiasis.1

(2) It is administered at a dosage level of one to two milligrams per pound of body weight, twice daily for 3 days.1

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.1


§520.82b Aminopropazine fumarate, neomycin sulfate tablets.

(a) Specifications. The drug is in tablet form. Each tablet contains both aminopropazine fumarate equivalent to 25 milligrams of aminopropazine base and neomycin sulfate equivalent to 50 milligrams of neomycin base.

(b) Sponsor. See No. 000661 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is used in dogs to control bacterial diarrhea caused by organisms susceptible to neomycin and to reduce smooth muscle contractions.1

(2) Cats—(i) Amount. 50 milligrams (5 to 10 milligrams per pound of body weight) once a day.

(i) Indications for use. Treatment of infections caused by susceptible organisms as follows: upper respiratory tract due to S. aureus, Streptococcus spp., and E. coli; genitourinary tract (cystitis) due to S. aureus, Streptococcus spp., and E. coli; and skin and soft tissue (abscesses, lacerations, 1These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.
and wounds) due to *S. aureus*, *Streptococcus* spp., *E. coli*, and *Pasteurella multocida*.

(iii) **Limitations.** Administer for 5 to 7 days or 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37319, Aug. 18, 1992, as amended at 60 FR 55658, Nov. 2, 1995]

### § 520.88b Amoxicillin trihydrate for oral suspension.

(a) **Specifications.** When reconstituted, each milliliter contains amoxicillin trihydrate equivalent to 50 milligrams of amoxicillin.

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

(1) **Conditions of use.—(i) Dogs.—**

(A) **Amount.** 5 milligrams per pound of body weight twice daily.

(B) **Indications for use.** Treatment of infections caused by susceptible strains of organisms as follows: respiratory tract (tonsillitis, tracheobronchitis) caused by *Staphylococcus aureus*, *Streptococcus* spp., *Escherichia coli*, and *Proteus mirabilis*; genitourinary tract (cystitis) caused by *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*; gastrointestinal tract (bacterial gastroenteritis) caused by *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*; and soft tissue infections (abscesses, lacerations, and wounds) due to *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*.

(C) **Limitations.** Use for 5 to 7 days or 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

(c) **Sponsors.** See Nos. 000856 and 051311 in §510.600(c) of this chapter.

(1) **Conditions of use. Dogs—**

(i) **Amount.** 5 milligrams per pound of body weight twice daily.

(ii) **Indications for use.** Treatment of bacterial dermatitis due to *S. aureus*, *Streptococcus* spp., *Staphylococcus* spp., and *E. coli*, and soft tissue infections (abscesses, wounds, lacerations) due to *S. aureus*, *Streptococcus* spp., *E. coli*, *P. mirabilis*, and *Staphylococcus* spp.

(iii) **Limitations.** Use for 5 to 7 days. Continue for 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]


### § 520.88c Amoxicillin trihydrate oral suspension.

(a) **Specifications.** Each 0.8-milliliter dose contains amoxicillin trihydrate equivalent to 40 milligrams of amoxicillin.

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

(c) **Related tolerances.** See §556.510 of this chapter.

(d) **Conditions of use. Swine**

(1) **Amount.** 40 milligrams orally, twice a day using a dosing pump.

(2) **Indications for use.** Treatment of porcine colibacillosis caused by *Escherichia coli* susceptible to amoxicillin.

(3) **Limitations.** Treat animals for 48 hours after all symptoms have subsided.