

§ 520.82

Dosage may be gradually increased up to a maximum of five times the suggested dosage. Oral administration of tablets may be preceded by subcutaneous or intramuscular use of the injectable form of the drug.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 53 FR 27851, July 25, 1988]

§ 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. 000061 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 1 to 2 milligrams per pound of body weight. The dosage can be repeated every 12 hours, as indicated.¹

(3) Not for use in animals intended for food purposes.

(4) For use only by or on the order of a licensed veterinarian.¹

[40 FR 13838, Mar. 27, 1975, as amended at 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997]

§ 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. 000061 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

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

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(2) It is administered at a dosage level of one to two tablets per 10 pounds 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

[40 FR 13838, Mar. 27, 1975, as amended at 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997]

§ 520.88 Amoxicillin oral dosage forms.

§ 520.88a Amoxicillin trihydrate film-coated tablets.

(a) *Specifications.* Each tablet contains amoxicillin trihydrate equivalent to 50, 100, 150, 200, or 400 milligrams of amoxicillin.

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

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 5 milligrams per pound of body weight, twice a day.

(ii) *Indications for use.* Treatment of infections of the respiratory tract (tonsillitis, tracheobronchitis), genitourinary tract (cystitis), gastrointestinal tract (bacterial gastroenteritis), and soft tissues (abscesses, lacerations, wounds), caused by susceptible strains of *Staphylococcus aureus*, *Streptococcus* spp., *Escherichia coli*, *Proteus mirabilis*, and bacterial dermatitis caused by *S. aureus*, *Streptococcus* spp., and *P. mirabilis*.

(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.

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

(ii) *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., *E. coli*, and *P. mirabilis*; gastrointestinal tract due to *E. coli*; and skin and soft tissue (abscesses, lacerations,

require bioequivalency and safety information.