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(2) *Indications for use.* Treatment of respiratory, urogenital, skin, and soft tissue infections and septicemia caused by pathogens susceptible to penicillin V potassium.

(3) *Limitations.* Administer orally 1 to 2 hours prior to feeding for maximum absorption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37326, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]

§ 520.1696d Penicillin V potassium tablets.

(a) *Specifications.* Each tablet contains penicillin V potassium equivalent to 125 milligrams (200,000 units) or 250 milligrams (400,000 units) of penicillin V.

(b) *Sponsors.* See Nos. 017144, 050604, and 053501 in § 510.600(c) of this chapter.

(c) *National Academy of Sciences/National Research Council (NAS/NRC) status.* These conditions of use were NAS/NRC reviewed and found 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.

(d) *Conditions of use. Dogs and Cats*—(1) *Amount.* 10 to 15 milligrams per pound of body weight every 6 to 8 hours.

(2) *Indications for use.* Treatment of respiratory, urogenital, skin and soft tissue infections and septicemia caused by pathogens susceptible to penicillin V potassium.

(3) *Limitations.* Administer orally 1 to 2 hours prior to feeding for maximum absorption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37327, Aug. 18, 1992, as amended at 59 FR 58775, Nov. 15, 1994]

§ 520.1720 Phenylbutazone oral dosage forms.

§ 520.1720a Phenylbutazone tablets and boluses.

(a) *Specifications.* Each tablet contains 100, 200, or 400 milligrams (mg), or 1 gram (g) of phenylbutazone. Each bolus contains 1, 2, or 4 gram g of phenylbutazone.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter, as follows:

(1) No. 000061 for use of 100- or 400-mg or 1-g tablets, or 2- or 4-g boluses, in dogs and horses.

(2) Nos. 000010 and 059130 for use of 100- or 200-mg or 1-g tablets in dogs and horses.

(3) Nos. 000856 and 061623 for use of 100-mg or 1-g tablets in dogs and horses.

(4) No. 055246 for use of 100-mg tablets in dogs.

(5) No. 000143 for use of 1-g tablets in horses.

(6) No. 058829 for use of 100-mg or 1-g tablets in dogs and horses.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 20 mg per pound of body weight daily.

(ii) *Indications for use.* For the relief of inflammatory conditions associated with the musculoskeletal system.

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

(2) *Horses*—(i) *Amount.* 1 to 2 g per 500 pounds of body weight daily.

(ii) *Indications for use.* For the relief of inflammatory conditions associated with the musculoskeletal system.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law prohibits the use of this drug in female dairy cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[73 FR 8192, Feb. 13, 2008, as amended at 74 FR 1146, Jan. 12, 2009; 76 FR 11331, Mar. 2, 2011]

EFFECTIVE DATE NOTE: At 76 FR 17777, Mar. 31, 2011, § 520.1720a was amended by removing and reserving paragraph (b)(4), effective April 11, 2011.

§ 520.1720b Phenylbutazone granules.

(a) *Specifications.* The drug is in granular form. It is packaged to contain either 8 grams of phenylbutazone per package or 1 gram of phenylbutazone per package.

(b) *Sponsor.* See 000061 in § 510.600(c) for 8-gram package, see 059320 for 1-gram package.

(c) *NAS/NRC status.* The conditions of use have been NAS/NRC reviewed and found effective. NADA's for approval of drugs for these conditions of use need

not include effectiveness data specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount.* 1 to 2 grams per 500 pounds of body weight, not to exceed 4 grams, daily, as required.

(ii) *Indications.* For the treatment of inflammatory conditions associated with the musculoskeletal system.

(iii) *Limitations.* Administer orally by adding to a portion of the usual grain ration. Use a relatively high dose for the first 48 hours, then gradually reduce to a maintenance level at the lowest level capable of producing the desired clinical response. Treated animals should not be slaughtered for food use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 18960, Mar. 27, 1981, as amended at 46 FR 48642, Oct. 2, 1981; 57 FR 2836, Jan. 24, 1992; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997; 65 FR 20731, Apr. 18, 2000]

§ 520.1720c Phenylbutazone paste.

(a) *Specifications*—(1) Each gram of paste contains 0.2 grams phenylbutazone.

(2) Each gram of paste contains 0.35 grams phenylbutazone.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter.

(1) Nos. 000061 and 010797 for use of product described in paragraph (a)(1) of this section.

(2) No. 064847 for use of product described in paragraph (a)(2) of this section.

(c) *Conditions of use in horses*—(1) *Amount.* 1 to 2 grams of phenylbutazone per 500 pounds of body weight, not to exceed 4 grams daily.

(2) *Indications for use.* For relief of inflammatory conditions associated with the musculoskeletal system.

(3) *Limitations.* Use a relatively high dose for the first 48 hours, then gradually reduce to a maintenance level of the lowest level capable of producing the desired clinical response. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 84762, Dec. 23, 1980, as amended at 58 FR 29777, May 24, 1993; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997; 68 FR 43926, July 25, 2003; 72 FR 60550, Oct. 25, 2007]

§ 520.1720d Phenylbutazone gel.

(a) *Specifications.* Each 30 grams of gel contains 4 grams of phenylbutazone.

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(c) *NAS/NRC status.* The conditions of use are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Conditions of use in horses*—(1) *Amount.* 1 to 2 grams of phenylbutazone per 500 pounds of body weight, not to exceed 4 grams daily.

(2) *Indications for use.* For relief of inflammatory conditions associated with the musculoskeletal system of horses.

(3) *Limitations.* Use a relatively high dose for the first 48 hours, then gradually reduce to a maintenance level at the lowest level capable of producing the desired clinical response. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[50 FR 13561, Apr. 5, 1985, as amended at 50 FR 49372, Dec. 2, 1985; 55 FR 8462, Mar. 8, 1990; 66 FR 14073, Mar. 9, 2001; 68 FR 4915, Jan. 31, 2003]

§ 520.1720e Phenylbutazone powder.

(a) *Specifications*—(1) Each 1.15 grams (g) of powder contains 1 g phenylbutazone.

(2) Each 10 g of powder contains 1 g phenylbutazone.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter.

(1) No. 027053 for use of product described in paragraph (a)(1) of this section.

(2) No. 057699 for use of product described in paragraph (a)(2) of this section.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 1 to 2 g (1 to 2 level scoops, using the scoop provided) per 500 pounds of body weight on a small amount of palatable feed, not exceed 4 g per animal daily.