

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

(ii) *Indications for use*. The drug is used for the relief of inflammatory conditions associated with a musculoskeletal system.¹

(iii) *Limitations*. Administer in three divided doses daily. Do not exceed a total daily dose of 800 milligrams regardless of body weight. Administer at a relatively high dosage level for the first 48 hours and then reduce gradually to a maintenance dosage level with the lowest dosage maintained at a level capable of producing the desired clinical response. Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

(2) *Horses*—(i) *Amount*. One to two grams per 500 pounds weight daily.¹

(ii) *Indications for use*. This drug is used for the relief of inflammatory conditions associated with the musculoskeletal system.¹

(iii) *Limitations*. Do not exceed a daily dosage of 4 grams per day. Administer at a relatively high dosage level for the first 48 hours and then reduce gradually to a maintenance dosage level with the lowest dosage maintained at the level capable of producing the desired clinical response. Not for use in animals intended for food purposes. Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[42 FR 44227, Sept. 2, 1977, as amended at 45 FR 10333, Feb. 15, 1980; 45 FR 14023, Mar. 4, 1980; 46 FR 48642, Oct. 2, 1981; 47 FR 30968, July 16, 1982; 50 FR 49372, Dec. 2, 1985; 52 FR 36023, Sept. 25, 1987; 54 FR 22885, May 30, 1989; 55 FR 8462, Mar. 8, 1990; 59 FR 53585, Oct. 25, 1994; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 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 050604 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]

§ 520.1720c Phenylbutazone paste.

(a) *Specifications*. The paste contains 20 percent phenylbutazone.

(b) *Sponsor*. See 000061 and 010797 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.

(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. Not for use in horses intended for food. 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]

¹See footnote 1 to § 520.1660b.