

Food and Drug Administration, HHS

§ 520.45a

(1) For No. 000856, use of 5-, 10-, or 25-milligram tablets as in paragraph (b) of this section.

(2) For No. 000010, use of 10- or 25-milligram tablets as in paragraph (c) of this section.

(b) *Conditions of use.* It is used in dogs and cats as follows:

(1) *Indications for use.* It is used in dogs and cats as a tranquilizer.

(2) *Amount.* Dogs: 0.25 to 1.0 milligram per pound of body weight; Cats: 0.5 to 1.0 milligram per pound of body weight.

(3) *Limitations.* The drug is administered orally. Dosage may be repeated as required. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c) *Conditions of use.* It is used in dogs as follows:

(1) *Indications for use.* It is used in dogs as an aid in tranquilization and as a preanesthetic agent.

(2) *Amount.* Dogs: 0.25 to 1.0 milligram per pound of body weight.

(3) *Limitations.* The drug is administered orally. Dosage may be repeated as required. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 44443, Sept. 4, 1981, as amended at 49 FR 49091, Dec. 18, 1984; 52 FR 666, Jan. 8, 1987; 53 FR 40727, Oct. 18, 1988; 56 FR 37473, Aug. 7, 1991; 62 FR 35075, June 30, 1997]

§ 520.44 Acetazolamide sodium soluble powder.

(a) *Specifications.* The drug is in a powder form containing acetazolamide sodium, USP equivalent to 25 percent acetazolamide activity.

(b) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in dogs as an aid in the treatment of mild congestive heart failure and for rapid reduction of intraocular pressure.¹

(2) It is administered orally at a dosage level of 5 to 15 milligrams per pound of body weight daily.¹

(3) For use only by or on the order of a licensed veterinarian.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 require bioequivalency and safety information.

§ 520.45 Albendazole oral dosage forms.

§ 520.45a Albendazole suspension.

(a)(1) *Specifications.* The product contains 11.36 percent albendazole.

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

(3) *Related tolerances.* See § 556.34 of this chapter.

(4) *Conditions of use in cattle—(i) Amount.* 4.54 milligrams per pound of body weight (10 milligrams per kilogram).

(ii) *Indications for use.* For removal and control of the following internal parasites of cattle: Adult liver flukes (*Fasciola hepatica*); heads and segments of tapeworms (*Moniezia benedeni*, *M. expansa*); adult and 4th stage larvae of stomach worms (brown stomach worms including 4th stage inhibited larvae (*Ostertagia ostertagi*), barberpole worm (*Haemonchus contortus*, *H. placei*), small stomach worm (*Trichostrongylus axei*)); adult and 4th stage larvae of intestinal worms (thread-necked intestinal worm (*Nematodirus spathiger*, *N. helvetianus*), small intestinal worm (*Cooperia punctata* and *C. oncophora*)); adult stages of intestinal worms (hookworm (*Bunostomum phlebotomum*), bankrupt worm (*Trichostrongylus colubriformis*), nodular worm (*Oesophagostomum radiatum*)); adult and 4th stage larvae of lungworms (*Dictyocaulus viviparus*).

(iii) *Limitations.* Administer as a single oral dose using dosing gun or dosing syringe. Do not slaughter within 27 days of last treatment. Do not use in female dairy cattle of breeding age: Do not administer to female cattle during first 45 days of pregnancy or for 45 days after removal of bulls. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(b)(1) *Specifications.* The product contains 4.55 or 11.36 percent albendazole.

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

(3) *Related tolerances.* See § 556.34 of this chapter.

(4) *Conditions of use in sheep—(i) Amount.* 7.5 milligrams per kilogram of body weight (3.4 milligrams per pound).

(ii) *Indications for use.* For removal and control of the following internal parasites of sheep: Adult liver flukes

§ 520.45b

(*Fasciola hepatica*, *Fascioloides magna*); heads and segments of common tapeworms (*Moniezia expansa*) and fringed tapeworm (*Thysanosoma actinioides*); adult and fourth stage larvae of stomach worms (brown stomach worm (*Ostertagia circumcincta* and *Marshallagia marshalli*), barberpole worm (*Haemonchus contortus*), small stomach worm (*Trichostrongylus axei*)); adult and fourth stage larvae of intestinal worms (thread-necked intestinal worm (*Nematodirus spathiger* and *N. filicollis*), Cooper's worm (*Cooperia oncophora*), bankrupt worm (*Trichostrongylus colubriformis*), nodular worm (*Oesophagostomum columbianum*), and large-mouth bowel worm (*Chabertia ovina*)); adult and larval stages of lungworms (*Dictyocaulus filaria*).

(iii) *Limitations.* Administer as a single oral dose using dosing gun or dosing syringe. Do not slaughter within 7 days of last treatment. Do not administer to ewes during first 30 days of pregnancy or for 30 days after removal of rams. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[54 FR 25115, June 13, 1989, as amended at 56 FR 50653, Oct. 8, 1991; 59 FR 65711, Dec. 21, 1994; 60 FR 55658, Nov. 2, 1995; 61 FR 4875, Feb. 9, 1996; 64 FR 1504, Jan. 11, 1999]

§ 520.45b Albendazole paste.

(a) *Specifications.* The product contains 30 percent albendazole.

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

(c) *Related tolerances.* See § 556.34 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount.* Equivalent to 4.54 milligrams per 1 pound of body weight (10 milligrams per kilogram).

(2) *Indications for use.* For removal and control of the following internal parasites of cattle: adult liver flukes (*Fasciola hepatica*); heads and segments of tapeworms (*Moniezia benedeni*, *M. expansa*); adult and 4th stage larvae of stomach worms (brown stomach worms including 4th stage inhibited larvae (*Ostertagia ostertagi*); barberpole worm (*Haemonchus contortus*, *H. placei*); small stomach worm (*Trichostrongylus axei*); adult and 4th stages larvae of intestinal worms (thread-necked intestinal worm (*Nematodirus spathiger*, *N.*

21 CFR Ch. I (4–1–00 Edition)

helvetianus); small intestinal worm (*Cooperia punctata* and *C. oncophora*); adult stages of intestinal worms (hookworm (*Bunostomum phlebotmum*); bankrupt worm (*Trichostrongylus colubriformis*), nodular worm (*Oesophagostomum radiatum*)); adult and 4th stage larvae of lungworms (*Dictyocaulus viviparus*).

(3) *Limitations.* Administer as a single oral dose. Do not slaughter within 27 days of last treatment. Do not use in female dairy cattle of breeding age. Do not administer to female cattle during first 45 days of pregnancy or for 45 days after removal of bulls. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[54 FR 51385, Dec. 15, 1989, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55658, Nov. 2, 1995]

§ 520.48 Altrenogest solution.

(a) *Specifications.* Each milliliter of altrenogest solution contains 2.2 milligrams of altrenogest.

(b) *Sponsor.* See No. 012799 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer orally at the rate of 1 milliliter per 110 pounds body weight (0.044 milligram per kilogram body weight). Give one dose daily for 15 consecutive days.

(2) *Indications for use.* For suppression of estrus in mares.

(3) *Limitations.* For oral use in horses only; avoid contact with the skin. Do not administer to horses intended for use as food. The drug is contraindicated for use in mares having a previous or current history of uterine inflammation (i.e., acute, subacute, or chronic endometritis). Natural or synthetic gestagen therapy may exacerbate existing low-grade or smoldering uterine inflammation into a fulminating uterine infection in some instances. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 40887, Sept. 12, 1983, as amended at 55 FR 26431, June 28, 1990; 64 FR 42597, Aug. 5, 1999]