Food and Drug Administration, HHS

§ 520.863 Ethylisobutrazine hydrochloride tablets.

(a) Specifications. Each tablet contains either 10 milligrams or 50 milligrams of ethylisobutrazine hydrochloride.

(b) Sponsor. See No. 000061 in §510.600(c) of this chapter.

(c) Conditions of use. (1) It is administered orally to dogs as a tranquilizer.1

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

(3) It is not to be used in conjunction with organophosphates and/or procaine hydrochloride because phenothiazine may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.1

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


§ 520.863a Febantel paste.

(a) Chemical name. Dimethyl [[2-[(methoxyacetyl)amino]-4-(phenylthio)phenyl] carbonimidoyl]bis [carbamate].

(b) Specifications. The drug is a paste containing 45.5 percent febantel.

(c) Sponsor. See No. 000859 in §510.600(c) of this chapter.

(d) Conditions of use—(1) Amount. Six milligrams per kilogram (2.73 milligrams per pound) of body weight in horses.

(2) Indications for use. For removal of large strongyles (Strongylus vulgaris, S. edentatus, S. equinus); ascarids (Parascaris equorum—sexually mature and immature); pinworms (Oxyuris equi—adult and 4th stage larva); and the various small strongyles in horses, foals, and ponies.

(3) Limitations. (i) The paste may be administered on the base of the tongue or well mixed into a portion of the normal grain ration.

(ii) [Reserved]

(iii) For animals maintained on premises where reinfection is likely to occur, retreatment may be necessary. For most effective results, retreat in 6 to 8 weeks.

(iv) Not for use in horses intended for food.

(v) Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.


§ 520.870 Etodolac.

(a) Specifications. Each tablet contains 150, 300, or 500 milligrams (mg) of etodolac.

(b) Sponsor. See No. 000010 in §510.600(c) of this chapter.

(c) [Reserved]

(d) Conditions of use—(1) Amount. Administer 10 to 15 mg per kilogram (4.5 to 6.8 mg per pound) of body weight per day orally.

(ii) Indications for use. For the management of pain and inflammation associated with osteoarthritis in dogs.

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

(2) [Reserved]


§ 520.903 Febantel oral dosage forms.

§ 520.903a Febantel oral dosage forms.

(a) Chemical name. Dimethyl [[2-[(methoxyacetyl)amino]-4-(phenylthio)phenyl] carbonimidoyl]bis [carbamate].

(b) Specifications. The drug is a suspension containing 45.5 percent febantel.

(c) Sponsor. See No. 000859 in §510.600(c) of this chapter.

(d) Conditions of use—(1) Amount. Six milligrams per kilogram (2.73 milligrams per pound) of body weight in horses.

(2) Indications for use. For removal of large strongyles (Strongylus vulgaris, S. edentatus, S. equinus); ascarids (Parascaris equorum—sexually mature and immature); pinworms (Oxyuris equi—adult and 4th stage larva); and the various small strongyles in horses, breeding

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.

§ 520.903b Febantel suspension.

(a) Specifications. The suspension contains 9.3 percent (2.75 grams per ounce) febantel.

(b) Sponsor. See 000859 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Amount. 3 milliliters per 100 pounds body weight or 1 fluid ounce per 1000 pounds (6 milligrams per kilogram body weight).

(2) Indications for use. For removal of ascarids (Parascaris equorum—adult and sexually immature), pinworms (Oxyuris equi—adult and 4th stage larvae), large strongyles (Strongylus vulgaris, S. edentatus, S. equinus), and the various small strongyles in horses, breeding
§ 520.903c  Febantel tablets.

(a) Specifications. Each scored tablet contains 27.2 milligrams of febantel for use in dogs, puppies, cats, and kittens or 163.3 milligrams of febantel for use in dogs, puppies, and cats.

(b) Sponsor. See 000859 in §510.600(c)(2) of this chapter.

(c) Conditions of use—(1) Amount—(i) Dogs and cats. Ten milligrams per kilogram body weight. Administer once daily for 3 consecutive days.

(ii) Puppies and kittens fewer than 6 months of age. Fifteen milligrams per kilogram body weight. Administer once daily for 3 consecutive days.

(2) Indications for use. (i) For removal of hookworms (Ancylostoma tubaeforme) and ascarids (Toxocara cati) in cats and kittens.

(ii) For removal of hookworms (Ancylostoma caninum and Uncinaria stenocephala), ascarids (Toxocara canis and Toxascaris leonina) and whipworms (Trichuris vulpis) in dogs and puppies.

(3) Limitations. Do not use in pregnant animals. Consider alternative therapy or use with caution in animals with pre-existing liver or kidney dysfunction. Administer to puppies and kittens on a full stomach. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[56 FR 50655, Oct. 8, 1991]

§ 520.905  Fenbendazole oral dosage forms.

§ 520.905a  Fenbendazole suspension.

(a) Specifications. Each milliliter of suspension contains 100 milligrams (mg) fenbendazole.