

§ 520.1288

(c) *Conditions of use.* (1) It is indicated in cases of hypothyroidism in dogs.

(2) It is administered orally to dogs at levels up to 12.8 micrograms per kilogram of body weight per day. Dosage should be adjusted according to the severity of the condition and the response of the patient. Dosage at the total replacement level (12.8µg per kilogram of body weight) should be considered for initiating therapy and then titrated downward for optimum maintenance effect. Twice daily administration is recommended.

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

[40 FR 13838, Mar. 27, 1975, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.1288 Lufenuron tablets.

(a) *Specifications*—(1) *Dogs.* Each tablet contains either 45, 90, 204.9, or 409.8 milligrams (mg) of lufenuron.

(2) *Cats.* Each tablet contains either 90, 135, 204.9 or 270 mg of lufenuron.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Minimum of 10 mg of lufenuron per kilogram (4.5 mg per pound (lb)) of body weight.

(2) *Indications for use.* For use in dogs and puppies, 6 weeks of age and older, for the prevention and control of flea populations. Lufenuron controls flea populations by preventing the development of flea eggs and does not kill adult fleas. Concurrent use of insecticides may be necessary for adequate control of adult fleas.

(3) *Limitations.* Administer tablet(s) after or in conjunction with a full meal to ensure adequate absorption. Administer tablet(s) once a month. All dogs and cats in a household should be treated to achieve maximum efficacy.

(d) *Conditions of use in cats*—(1) *Amount.* Minimum of 30 mg of lufenuron per kilogram (13.6 mg/lb) of body weight.

(2) *Indications for use.* For use in cats and kittens, 6 weeks of age and older, for the control of flea populations. Lufenuron controls flea populations by preventing the development of flea eggs and does not kill adult fleas. Concurrent use of insecticides may be nec-

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essary for adequate control of adult fleas.

(3) *Limitations.* Administer tablet(s) after or in conjunction with a full meal to ensure adequate absorption. Administer tablet(s) once a month. All dogs and cats in a household should be treated to achieve maximum efficacy.

[63 FR 52968, Oct. 2, 1998]

§ 520.1289 Lufenuron suspension.

(a) *Specifications.* Each individual dose pack contains either 135 or 270 milligrams of lufenuron.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats*—(1) *Amount.* Minimum of 13.6 milligrams per pound of body weight (30 milligrams per kilogram). Recommended dose of 135 milligrams for up to 10 pounds of body weight or 270 milligrams for 11 to 20 pounds. Cats over 20 pounds are provided the appropriate combination of packs.

(2) *Indications for use.* For control of flea populations.

(3) *Limitations.* For oral use in cats 6 weeks of age or older, once a month, mixed with food. Administer in conjunction with a full meal to ensure adequate absorption. Treat all cats in the household to ensure maximum benefits. Because the drug has no effect on adult fleas, the concurrent use of insecticides that kill adults may be necessary depending on the severity of the infestation.

[60 FR 20402, Apr. 26, 1995, as amended at 62 FR 8371, Feb. 25, 1997]

§ 520.1310 Marbofloxacin tablets.

(a) *Specifications.* Each tablet contains 25, 50, 100, or 200 milligrams (mg) marbofloxacin.

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

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount.* 1.25 mg per pound (lb) of body weight once daily, but may be increased to 2.5 mg/lb of body weight once daily.

(2) *Indications for use.* For the treatment of infections in dogs and cats associated with bacteria susceptible to marbofloxacin.

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

licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

[64 FR 39919, July 23, 1999, as amended at 66 FR 46369, Sept. 5, 2001]

§ 520.1320 Mebendazole oral.

(a) *Chemical name.* Methyl 5-benzoyl-benzimidazole-2-carbamate.

(b) *Specifications.* As oral powder: Each gram contains either 40 or 166.7 milligrams of mebendazole. As oral paste: Each gram contains 200 milligrams of mebendazole. As oral suspension: Each milliliter contains 33.3 milligrams of mebendazole.

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

(d) *Conditions of use*—(1) *Horses*—(i) *Amount.* 1 gram of mebendazole per 250 pounds of body weight per dose, as an oral powder, paste or suspension.

(ii) *Indications for use.* It is used in horses for treatment of infections caused by large roundworms (*Parascaris equorum*); large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*); small strongyles; and mature and immature (4th larval stage pinworms (*Oxyuris equi*)).

(iii) *Limitations*—(a) *Oral powder.* The drug is given by sprinkling directly on the grain portion of the ration or dissolving in 2 to 4 pints of water and administering by stomach tube. The drug is compatible with carbon disulfide, which can be used concurrently for both control (*Gastrophilus spp.*). Routine cautions regarding the use of carbon disulfide must be observed. Do not administer to horses intended for use as food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b) *Oral paste.* The drug is given by dosing gun (syringe), inserting the tip of the gun at the interdental space in the horse's mouth and depositing the paste on the animal's tongue. The hand is placed under the animal's jaw, and the head is raised to assure that the paste is deposited on the roof of the mouth. Not for use in horses intended for food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(c) *Oral suspension.* The drug is administered by stomach tube. Not for horses intended for food use. Federal

law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dogs*—(i) *Amount.* One hundred milligrams of mebendazole per 10 pounds of body weight, once daily for 3 days, as an oral powder.

(ii) *Indications for use.* The drug is used for treatment of infections of roundworms (*Toxocara canis*), hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*), whipworms (*Trichuris vulpis*), and tapeworms (*Taenia pisiformis*).

(iii) *Limitations.* Administer as an oral powder by mixing with a small quantity of food, preferably before the regular meal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[42 FR 61255, Dec. 2, 1977, as amended at 43 FR 35686, Aug. 11, 1978; 45 FR 3574, Jan. 18, 1980; 46 FR 47218, Sept. 25, 1981; 46 FR 53658, Oct. 30, 1981; 62 FR 61625, Nov. 19, 1997]

§ 520.1326 Mebendazole and trichlorfon oral dosage forms.

§ 520.1326a Mebendazole and trichlorfon powder.

(a) *Specifications.* Each gram of powder contains 83.3 milligrams of mebendazole and 375.0 milligrams of trichlorofon.

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

(c) *Conditions of use.* *Horses*—(1) *Amount.* 8.8 milligrams of mebendazole and 40 milligrams of trichlorofon per kilogram of body weight.

(2) *Indications for use.* It is used in horses for the treatment of infections of bots (*Gastrophilus intestinalis* and *G. nasalis*), large roundworms (*Parascaris equorum*), large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*), small strongyles, and pinworms (*Oxyuris equi*).

(3) *Limitations.* Administer orally as an individual dose by stomach tube or thoroughly mixed in the ground grain portion of the ration to be consumed in one feeding. Discard treated feed not consumed. Do not administer more than once every 30 days. Do not treat sick or debilitated animals, foals under 4 months of age, or mares in the last month of pregnancy. Trichlorofon is a cholinesterase inhibitor. Do not administer simultaneously or within a few