

§ 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