Food and Drug Administration, HHS

§ 520.1044 Gentamicin sulfate oral dosage forms.

§ 520.1044a Gentamicin sulfate oral solution.

(a) Specifications. Each milliliter of aqueous solution contains gentamicin sulfate equivalent to 50 milligrams of gentamicin.

(b) Sponsor. See Nos. 000061 and 054925 in §510.600(c) of this chapter.

(d)(1) of this section; and for syrup in paragraph (a)(4) of this section for conditions of use in paragraphs (d)(2)(i) and (d)(2)(ii)(A).

(2) Amount. 0.5 mg of flunixin per pound of body weight per day.

(2) Indications for use. For alleviation of inflammation and pain associated with musculoskeletal disorders.

(3) Limitations. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[76 FR 53051, Aug. 25, 2011]

§ 520.980 Fluoxetine.

(a) Specifications. Each chewable tablet contains 8, 16, 32, or 64 milligrams (mg) fluoxetine hydrochloride.

(b) Sponsor. See No. 000986 in § 510.600 of this chapter.

(c) Conditions of use in dogs—(1) Amount. 1 to 2 mg per kilogram body weight once daily.

(2) Indications for use. For the treatment of canine separation anxiety in conjunction with a behavior modification plan.

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

[72 FR 6463, Feb. 12, 2007]

§ 520.1010 Furosemide.

(a) Specifications. (1) Each tablet contains 12.5 or 50 milligrams (mg) furosemide.

(2) Each bolus contains 2 grams (g) furosemide.

(3) Each packet of powder contains 2 g furosemide.

(4) Each milliliter of syrup contains 10 mg furosemide.

(b) Sponsors. See sponsor numbers in §510.600(c) of this chapter for use of dosage forms and strengths listed in paragraph (a) of this section for uses as in paragraph (d) of this section.

(1) No. 000010 for tablets in paragraph (a)(1) of this section for conditions of use in paragraphs (d)(2)(i), (d)(2)(ii)(A), and (d)(3) of this section.

(2) No. 000061 for tablets in paragraph (a)(1) of this section for conditions of use in paragraphs (d)(2)(i), (d)(2)(ii)(A), and (d)(3) of this section; for boluses in paragraph (a)(2) of this section and powder in paragraph (a)(3) of this section for conditions of use in paragraph (d)(1) of this section; and for syrup in paragraph (a)(4) of this section for conditions of use in paragraphs (d)(2)(i) and (d)(2)(ii)(A).

(3) Nos. 058829 and 059130 for use of syrup in paragraph (a)(4) of this section for conditions of use in paragraph (d)(2)(i) and (d)(2)(ii)(A) of this section.

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

(d) Conditions of use. It is used as follows:

(1) Cattle—(i) Amount. 1 to 2 mg per pound (lb) body weight using powder, or one 2-g bolus per animal, per day.

(ii) Indications for use. For treatment of physiological parturient edema of the mammary gland and associated structures.

(iii) Limitations. Treatment not to exceed 48 hours post-parturition. Milk taken during treatment and for 48 hours after the last treatment must not be used for food. Cattle must not be slaughtered for food within 48 hours following last treatment.

(2) Dogs—(i) Amount. 1 to 2 mg/lb body weight, once or twice daily.

(ii) Indications for use.—(A) For treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

(B) For treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency.

(3) Cats—(i) Amount. 1 to 2 mg/lb body weight, once or twice daily.

(ii) Indications for use. For treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.