Food and Drug Administration, HHS

§ 522.800 Droperidol and fentanyl citrate injection.

(a) Specifications. Droperidol and fentanyl citrate injection is a sterile solution containing 20 milligrams of droperidol and 0.4 milligram of fentanyl citrate per cubic centimeter.

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

(c) Conditions of use. (1) It is used in dogs as an analgesic and tranquilizer and for general anesthesia.

(2) It is administered to horses at a dosage level of 25 mg per hundred pounds of body weight. It is administered to dogs and cats at a dosage level of 0.5 to 1 mg per pound of body weight. Doses may be repeated at 8 to 12 hours, if necessary, to produce desired effect. Intravenous route is not recommended for dogs and cats and should be injected slowly in horses. Intramuscular and subcutaneous administration should be by divided injection sites.1

(3) Not for use in horses intended for food.1

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


§ 522.784 Doxylamine succinate injection.

(a) Specifications. Each milliliter of the drug contains 11.36 mg of doxylamine succinate.

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

(c) Conditions of use. (1) The drug is used in conditions in which antihistaminic therapy may be expected to alleviate some signs of disease in horses, dogs, and cats.1

(2) It is administered to horses at a dosage level of 25 mg per hundred pounds of body weight. It is administered to dogs and cats at a dosage level of 0.5 to 1 mg per pound of body weight. Doses may be repeated at 8 to 12 hours, if necessary, to produce desired effect. Intravenous route is not recommended for dogs and cats and should be injected slowly in horses. Intramuscular and subcutaneous administration should be by divided injection sites.1

(3) Not for use in horses intended for food.1

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


§ 522.778 Doxycycline hyclate.

(a) Specifications. Doxycycline hyclate solution contains 8.5 percent doxycycline activity. A syringe of N-methyl-2-pyrrolidone and poly (DL-lactide) mixed with a syringe of doxycycline produces 0.5 milliliter of solution.

(b) Sponsor. See 000009 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) Conditions of use. (1) Dogs—(i) Amount. Apply subgingivally to periodontal pocket(s) of affected teeth.

(ii) Indications for use. For treatment and control of periodontal disease.

(iii) Limitations. Do not use in dogs less than 1-year old. Use of tetracyclines during tooth development has been associated with permanent discoloration of teeth. Do not use in pregnant bitches. Use in breeding dogs has not been evaluated. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 522.784 Doxylamine succinate injection.

(a) Specifications. Each milliliter of the drug contains 11.36 mg of doxylamine succinate.

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

(c) Conditions of use. (1) The drug is used in conditions in which antihistaminic therapy may be expected to alleviate some signs of disease in horses, dogs, and cats.1

(2) It is administered to horses at a dosage level of 25 mg per hundred pounds of body weight. It is administered to dogs and cats at a dosage level of 0.5 to 1 mg per pound of body weight. Doses may be repeated at 8 to 12 hours, if necessary, to produce desired effect. Intravenous route is not recommended for dogs and cats and should be injected slowly in horses. Intramuscular and subcutaneous administration should be by divided injection sites.1

(3) Not for use in horses intended for food.1

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


§ 522.800 Droperidol and fentanyl citrate injection.

(a) Specifications. Droperidol and fentanyl citrate injection is a sterile solution containing 20 milligrams of droperidol and 0.4 milligram of fentanyl citrate per cubic centimeter.

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

(c) Conditions of use. (1) It is used in dogs as an analgesic and tranquilizer and for general anesthesia.

(2) It is administered as follows:

These 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.
§ 522.810  Embutramide, chloroquine, and lidocaine solution.

(a) Specifications. Each milliliter (mL) of solution contains: (1) 135 milligrams (mg) embutramide; 45 mg chloroquine phosphate, U.S.P.; and 1.9 mg lidocaine, U.S.P.

(b) Sponsor. See No. 000859 in §510.901(c) of this chapter.

(c) Conditions of use—(1) Amount. One mL per 5 pounds of body weight.

(2) Indications for use. For euthanasia.

(3) Limitations. Not for use in animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[70 FR 38337, June 23, 2005, as amended at 78 FR 17597, Mar. 22, 2013]

§ 522.812  Enrofloxacin.

(a) Specifications. Each milliliter (mL) of solution contains:

(1) 22.7 milligrams (mg) enrofloxacin or

(2) 100 mg enrofloxacin.

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

(c) Related tolerance. See §556.226 of this chapter.

(d) Special considerations. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extra-label use of this drug in food-producing animals.

(e) Conditions of use—(1) Dogs. Use the product described in paragraph (a)(1) of this section as follows:

(i) Amount. 2.5 mg per kilogram (/kg) of body weight (1.13 mg per pound) as a single, intramuscular, initial dose followed by use of tablets twice daily for 2 to 3 days beyond cessation of clinical signs to a maximum of 10 days.

(ii) Indications for use. For the management of diseases associated with bacteria susceptible to enrofloxacin.

(i) Amount—(A) Single-dose therapy: For treatment of bovine respiratory disease (BRD), administer 7.5 to 12.5 mg/kg of body weight (3.4 to 5.7 mL per 100 pounds (100 lb)) once by subcutaneous injection. For control of BRD, administer 7.5 mg/kg of body weight (3.4 mL/100 lb) once by subcutaneous injection.

(2) Multiple-day therapy: For treatment of BRD, administer 2.5 to 5.0 mg/kg of body weight (1.1 to 2.3 mL/100 lb) by subcutaneous injection. Treatment should be repeated at 24-hour intervals for 3 days. Additional treatments may be given on days 4 and 5 to animals that have shown clinical improvement but not total recovery.

(B) Multiple-day therapy: For treatment of BRD, administer 2.5 to 5.0 mg/kg of body weight (1.1 to 2.3 mL/100 lb) by subcutaneous injection. Treatment should be repeated at 24-hour intervals for 3 days. Additional treatments may be given on days 4 and 5 to animals that have shown clinical improvement but not total recovery.

(ii) Indications for use—(A) Single-dose therapy: For the treatment of BRD associated with Mannheimia haemolytica, Pasteurella multocida, Histophilus somni, and Mycoplasma bovis in beef and non-lactating dairy cattle; for the control of BRD in beef and non-lactating dairy cattle at high risk of developing BRD.