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established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(3) Steers fed in confinement for slaughter—(i) Amount. Reimplant 200 mg progesterone and 20 mg estradiol benzoate on approximately day 70 following an initial implant of 100 mg progesterone and 10 mg estradiol benzoate or 200 mg progesterone and 20 mg estradiol benzoate.

(ii) Indications for use. For additional improvement in rate of weight gain.

(iii) Limitations. For subcutaneous ear implantation. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.


§ 522.1962 Promazine hydrochloride.

(a) Specifications. Each milliliter of solution contains 50 milligrams (mg) promazine hydrochloride.

(b) Sponsors. See sponsors in §510.600(c) of this chapter for use as in paragraph (c) of this section:

(1) No. 000856 for use as in paragraphs (c)(1)(i)(A), (c)(1)(ii)(A), (c)(1)(iii), and (c)(2) of this section.

(2) No. 061623 for use as in paragraphs (c)(1)(i)(B), (c)(1)(ii)(B), and (c)(1)(iii) of this section.

(c) Conditions of use—(1) Horses—(i) Amount—(A) 0.2 to 0.5 milligrams per pounds (mg/lb) body weight intramuscularly or intravenously every 4 to 6 hours.

(B) 0.2 to 0.5 mg/lb body weight intravenously as required.

(ii) Indications for use—(A) For use as a tranquilizer, preanesthetic, or for minor operative procedures in conjunction with local anesthesia, as adjunctive therapy for tetanus, and as an antiemetic prior to worming; or to prevent motion sickness in dogs.

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


§ 522.2002 Propiopromazine hydrochloride injection.

(a) Chemical name. 1-Propanone, 1-[10-[3-(dimethylamino) propyl]phenothiazine-2-yl]-, monohydrochloride.

(b) Specifications. Propiopromazine hydrochloride injection contains 5 or 10 milligrams of the drug in each milliliter of sterile aqueous solution.

(c) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(d) Conditions of use. (1) It is administered either intravenously or intramuscularly to dogs and cats for tranquilization at a dosage level of 0.05–0.5 milligram per pound of body weight and is also administered intravenously to dogs and cats as a preanesthetic at a dosage level of 0.25 milligram per pound of body weight.

(2) It is not to be used in conjunction with organophosphates and/or procaine hydrochloride since phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.

(3) For use only by or on the order of a licensed veterinarian.


§ 522.2005 Propofol.

(a) Specifications. Each milliliter of emulsion contains 10 milligrams (mg) propofol.

(b) Sponsors. See sponsor numbers in §510.600(c) of this chapter.

(1) No. 059130 for use as in paragraphs (c)(1), (c)(2)(i), and (c)(3) of this section.

(2) No. 000074 for use as in paragraphs (c)(1), (c)(2)(i), and (c)(3) of this section.
(c) Conditions of use in dogs and cats—
(1) Amount. Administer by intravenous injection according to label directions. The use of preanesthetic medication reduces propofol dose requirements.
(2) Indications for use—(i) As a single injection to provide general anesthesia for short procedures; for induction and maintenance of general anesthesia using incremental doses to effect; for induction of general anesthesia where maintenance is provided by inhalant anesthetics.
(ii) For the induction and maintenance of anesthesia and for induction of anesthesia followed by maintenance with an inhalant anesthetic.

(a) Specifications. Each milliliter of sterile solution contains 1 milligram of prostalene.
(b) Sponsor. No. 000856 in § 510.600(c) of this chapter.
(c) Conditions of use—Horses. (1) It is used in mares for the control of estrus.
(2) It is administered at a dose of 5 micrograms per kilogram of body weight as a single subcutaneous injection.
(3) Not for use in horses intended for food.
(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.2063 Pyrilamine maleate injection.
(a) Specifications. The drug is a sterile aqueous solution with each milliliter containing 20 milligrams of pyrilamine maleate.
(b) Sponsors. See No. 000061 in § 510.600(c) of this chapter for uses in paragraph (c)(2)(i) of this section; see No. 061623 in § 510.600(c) of this chapter for uses in paragraph (c)(2)(ii) of this section.
(c) Conditions of use. (1) It is intended for treating horses in conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease.1
(2)(i) It is administered intramuscularly, subcutaneously, or intravenously. Local injection at the site of insect bites may be indicated in severe cases. Intravenous injections must be given slowly to avoid symptoms of overdosage. Dosage may be repeated every 6 to 12 hours whenever necessary. Horses, 40 to 60 milligrams per 100 pounds body weight; foals, 20 milligrams per 100 pounds body weight.
(ii) It is administered intravenously. Intravenous injections must be given slowly to avoid symptoms of overdosage.Dosage may be repeated every 6 to 12 hours if necessary. Horses, 40 to 60 milligrams per 100 pounds body weight; foals, 20 milligrams per 100 pounds body weight.
(3) Do not use in horses intended for food purposes.
(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.2076 Romifidine.
(a) Specifications. Each milliliter of solution contains 10 milligrams (mg) romifidine hydrochloride.
(b) Sponsor. See No. 000010 in § 510.600(c) of this chapter.
(c) Conditions of use in horses—(1) Amount. 40 to 120 micrograms per kilogram of body weight (mcg/kg BW) intravenously for sedation and analgesia; 100 mcg/kg BW intravenously as a preanesthetic.
(2) Indications for use. For use as a sedative and analgesic to facilitate handling, clinical examinations, clinical procedures, and minor surgical procedures in adult horses; and for use as a preanesthetic prior to the induction of general anesthesia in adult horses.

1These conditions are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalence and safety information.