

Food and Drug Administration, HHS

§ 522.1145

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

[74 FR 61516, Nov. 25, 2009]

§ 522.1085 Guaifenesin sterile powder.

(a) *Specifications.* It is a sterile powder containing guaifenesin.

(b) *Sponsor.* See Nos. 000856 and 037990 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is indicated for intravenous use as a muscle relaxant in horses.

(2) A solution is prepared by dissolving the drug in sterile water for injection to make a solution containing 50 milligrams of guaifenesin per milliliter of solution. It is administered by rapid intravenous infusion at a fixed dosage of 1 milliliter of prepared solution per pound of body weight.

(3) Not to be used in horses intended for food.

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

[49 FR 48039, Dec. 10, 1984, as amended at 60 FR 27223, May 23, 1995; 67 FR 67521, Nov. 6, 2002]

§ 522.1086 Guaifenesin injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 50 milligrams of guaifenesin and 50 milligrams of dextrose.

(b) *Sponsor.* See Nos. 037990 and 059130 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use.* (1) The drug is used intravenously in horses as a skeletal muscle relaxant.

(2) Administer rapidly at a dosage of 1 milliliter per pound of body weight.

(3) No to be used in horses intended for food.

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

[60 FR 27223, May 23, 1995, as amended at 63 FR 29352, May 29, 1998]

§ 522.1125 Hemoglobin glutamer-200 (bovine).

(a) *Specifications.* Each 125 milliliter bag contains 13 grams per deciliter of polymerized hemoglobin of bovine origin in modified Lactated Ringer's Solu-

tion. It is a sterile, clear, dark purple solution.

(b) *Sponsor.* See No. 063075 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use—*(1) *Amount.* One-time dose of 10 to 30 milliliters per kilogram of body weight administered intravenously at a rate of up to 10 milliliters per kilogram per hour.

(2) *Indications for use.* For the treatment of anemia in dogs by increasing systemic oxygen content (plasma hemoglobin concentration) and improving the clinical signs associated with anemia, regardless of the cause of anemia (hemolysis, blood loss, or ineffective erythropoiesis).

(3) *Limitations.* For intravenous use only. Overdosage or an excessive rate of administration (greater than 10 milliliters per kilogram per hour) may result in circulatory overload. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[63 FR 11598, Mar. 10, 1998, as amended at 65 FR 20732, Apr. 18, 2000]

§ 522.1145 Hyaluronate sodium.

(a)(1) *Specifications.* Each milliliter of sterile aqueous solution contains 10 milligrams of hyaluronate sodium.

(2) *Sponsor.* See 000009 in § 510.600(c).

(3) *Conditions of use—*(i) *Amount.* Small and medium-size joints (carpal, fetlock)—20 milligrams; larger joint (hock)—40 milligrams.

(ii) *Indications for use.* Treatment of joint dysfunction in horses due to non-infectious synovitis associated with equine osteoarthritis.

(iii) *Limitations.* For intra-articular injection in horses only. Treatment may be repeated at weekly intervals for a total of three treatments. 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.

(b)(1) *Specifications.* Each milliliter of sterile aqueous solution contains 5 milligrams of hyaluronate sodium.

(2) *Sponsor.* See 053501 in § 510.600(c) of this chapter.

(3) *Conditions of use—*(i) *Amount.* Small and medium-size joints (carpal, fetlock)—10 milligrams; larger joint (hock)—20 milligrams.

(ii) *Indications for use.* Treatment of joint dysfunction in horses due to non-infectious synovitis associated with equine osteoarthritis.

(iii) *Limitations.* For intraarticular injection in horses only. Treatment may be repeated at weekly intervals for a total of four treatments. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c)(1) *Specifications.* Each milliliter of sterile aqueous solution contains 10 milligrams of hyaluronate sodium.

(2) *Sponsor.* See No. 000010 in §510.600(c) of this chapter.

(3) *Conditions of use—(i) Amount.* Small and medium-size joints (carpal, fetlock)—20 milligrams.

(ii) *Indications for use.* Treatment of carpal or fetlock joint dysfunction in horses due to acute or chronic non-infectious synovitis associated with equine osteoarthritis.

(iii) *Limitations.* For intraarticular injection in horses only. Treatment may be repeated after 1 or more weeks but not to exceed 2 injections per week for a total of 4 weeks. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d)(1) *Specifications.* Each milliliter of sterile aqueous solution contains 10 milligrams of hyaluronate sodium.

(2) *Sponsor.* See 000061 in §510.600(c) of this chapter.

(3) *Conditions of use—(i) Amount.* 50 milligrams in carpal and fetlock joints.

(ii) *Indications for use.* For treatment of equine carpal and fetlock joint dysfunction caused by traumatic and/or degenerative joint disease of mild to moderate severity.

(iii) *Limitations.* For intraarticular injection in horses only. Not for use in horses intended for food. Not intended for use in breeding animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e)(1) *Specifications.* Each milliliter of solution contains:

(i) 10 milligrams (mg) hyaluronate sodium; or

(ii) 10 mg hyaluronate sodium with benzyl alcohol as a preservative.

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

(3) *Conditions of use in horses—(i) Amount.* 20 mg of the product described in paragraph (e)(1)(i) of this section by intra-articular injection into the carpus or fetlock; or 40 mg of the product described in paragraph (e)(1)(i) or (e)(1)(ii) of this section by slow intravenous injection into the jugular vein. Treatment may be repeated at weekly intervals for a total of three treatments.

(ii) *Indications for use.* For treatment of carpal or fetlock joint dysfunction due to noninfectious synovitis associated with equine osteoarthritis.

(iii) *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.

(f)(1) *Specifications.* Each milliliter of sterile aqueous solution contains 11 milligrams of hyaluronate sodium.

(2) *Sponsor.* See 060865 in §510.600(c).

(3) *Conditions of use—(i) Amount.* Small and medium-size joints (carpal, fetlock)—22 milligrams; larger joint (hock)—44 milligrams.

(ii) *Indications for use.* Treatment of joint dysfunction in horses due to non-infectious synovitis associated with equine osteoarthritis.

(iii) *Limitations.* For intra-articular injection in horses only. Treatment may be repeated at weekly intervals for a total of three treatments. 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.

[49 FR 45124, Nov. 15, 1984, as amended at 51 FR 11438, Apr. 3, 1986; 51 FR 25032, July 10, 1986; 53 FR 19773, May 31, 1988; 53 FR 22297, June 15, 1988; 56 FR 50814, Oct. 9, 1991; 57 FR 2837, Jan. 24, 1992; 59 FR 33198, June 28, 1994; 61 FR 59003, Nov. 20, 1996; 63 FR 59216, Nov. 3, 1998; 71 FR 1689, Jan. 11, 2006; 71 FR 39204, July 12, 2006; 75 FR 1274, Jan. 11, 2010; 75 FR 10167, Mar. 5, 2010]

§522.1150 Hydrochlorothiazide injection.

(a) *Specifications.* Each milliliter contains 25 milligrams of hydrochlorothiazide.

(b) *Sponsor.* See No. 050604 in §510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* 5 to 10 milliliters (125 to 250 milligrams) intravenously or intramuscularly once or twice a day. After onset of diuresis,