

§ 522.150

(2) *Indications for use.* To reverse clinical effects of the sedative and analgesic agent medetomidine hydrochloride.

(3) *Limitations.* For intramuscular use only. Not recommended for use in pregnant or lactating animals, or animals intended for breeding. Atipamezole has not been evaluated in breeding animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[61 FR 48830, Sept. 17, 1996, as amended at 64 FR 71640, Dec. 22, 1999]

§ 522.150 Azaperone injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 40 milligrams of azaperone.

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

(c) *Conditions of use*—(1) *Indications for use.* Control of aggressiveness when mixing or regrouping weanling or feeder pigs weighing up to 80 pounds.

(2) *Dosage.* 2.2 milligrams per kilogram (1 milligram per pound).

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

[48 FR 48229, Oct. 18, 1983, as amended at 62 FR 61625, Nov. 19, 1997]

§ 522.161 Betamethasone acetate and betamethasone disodium phosphate aqueous suspension.

(a) *Chemical names.* Betamethasone acetate: 9- α -Fluoro-16- β -methylprednisolone - 21 - acetate (C₂₄H₃₁FO₆). Betamethasone disodium phosphate: 9- α -Fluoro-16- β -methylprednisolone-21-disodium phosphate (C₂₂H₂₈FNa₂O₈P).

(b) *Specifications.* The drug is a sterile aqueous suspension and each cubic centimeter contains: 12 milligrams of betamethasone acetate (equivalent to 10.8 milligrams of betamethasone), 3.9 milligrams of betamethasone disodium phosphate (equivalent to 3 milligrams of betamethasone), 2 milligrams of dibasic sodium phosphate, 5 milligrams of sodium chloride, 0.1 milligram of disodium EDTA, 0.5 milligram of polysorbate 80, 9 milligrams of benzyl alcohol, 5 milligrams of sodium carboxymethylcellulose, 1.8 milligrams of methylparaben, 0.2 milligram of propylparaben, hydrochloric acid and/

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or sodium hydroxide to adjust pH, and water for injection q.s.

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

(d) *Conditions of use.* It is used or intended for use by intra-articular injection of horses for the treatment of various inflammatory joint conditions; for example, acute and traumatic lameness involving the carpal and fetlock joints. Administer from 2.5 to 5 cubic centimeters per dose. Dose may be repeated when necessary depending upon the duration of relief obtained. Not for use in horses intended for food. For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 52 FR 7832, Mar. 13, 1987]

§ 522.163 Betamethasone dipropionate and betamethasone sodium phosphate aqueous suspension.

(a) *Specifications.* Betamethasone dipropionate and betamethasone sodium phosphate aqueous suspension is a sterile aqueous suspension. Each milliliter of the suspension contains the equivalent of 5 milligrams of betamethasone as betamethasone dipropionate and 2 milligrams of betamethasone as betamethasone sodium phosphate.

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

(c) *Conditions of use*—(1) *Dogs.* (i) It is used as an aid in the control of pruritus associated with dermatoses.

(ii) It is administered by intramuscular injection at a dosage of 0.25 to 0.5 milliliter per 20 pounds of body weight, depending on the severity of the condition. Frequency of dosage depends on recurrence of pruritic symptoms. Dosage may be repeated every 3 weeks or when symptoms recur, not to exceed a total of 4 injections.

(2) *Horses.* (i) It is used as an aid in the control of inflammation associated with various arthropathies.

(ii) It is administered aseptically by intraarticular injection at a dosage of 2.5 to 5 milliliters per joint, depending on the severity of the condition and the joint size. Dosage may be repeated upon recurrence of clinical signs. Injection into the joint cavity should be preceded by withdrawal of synovial fluid.

(iii) Not for use in horses intended for food.

(3) *Clinical and experimental data.* It has been demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

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

[40 FR 13858, Mar. 27, 1975, as amended at 41 FR 27316, July 2, 1976; 52 FR 7832, Mar. 13, 1987]

§ 522.204 Boldenone undecylenate injection.

(a) *Specifications.* Each milliliter contains 25 or 50 milligrams of boldenone undecylenate in a sesame oil base.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is intended for use as an aid in treating debilitated horses following disease or overwork and overexertion when an improvement in weight, hair coat, or general physical condition is desired. The drug is given only as adjunctive therapy to other specific and supportive therapy for diseases, surgical cases, and traumatic injuries. Optimal results can be expected only when good management and feeding practices are followed.

(2) It is administered intramuscularly at a dosage level of 0.5 milligram per pound of body weight. Treatment may be repeated at 3-week intervals.

(3) For use in horses only. Do not administer to horses intended for use as food. The effectiveness of the drug in stallions and pregnant mares has not been established, nor has the drug been shown not to be teratogenic in pregnant mares; therefore, this drug should not be used in stallions and pregnant mares.

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

[40 FR 13858, Mar. 27, 1975, as amended at 50 FR 41489, Oct. 11, 1985]

§ 522.234 Butamisol hydrochloride.

(a) *Specifications.* The drug contains 11 milligrams of butamisol per milliliter in a solution consisting of 70 percent propylene glycol, 4 percent benzyl alcohol and distilled water.

(b) *Sponsor.* See Nos. 000859 and 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is administered by subcutaneous injection to dogs for the treatment of infections with whipworms (*Trichuris vulpis*), and the hookworm (*Ancylostoma caninum*).

(2) The drug is administered subcutaneously at the rate of 0.1 milliliter per pound of body weight. In problem cases, retreatment for whipworms may be necessary in approximately 3 months. For hookworms, a second injection should be given 21 days after the initial treatment.

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

[43 FR 15625, Apr. 14, 1978. Redesignated at 43 FR 60883, Dec. 29, 1978, and amended at 45 FR 29789, May 6, 1980; 51 FR 19329, May 29, 1986; 67 FR 63055, Oct. 10, 2002]

§ 522.246 Butorphanol tartrate injection.

(a) *Specifications.* Each milliliter of aqueous solution contains either 0.5, 2 or 10 milligrams of butorphanol (as butorphanol tartrate).

(b) *Sponsors.* Approval to firms identified in § 510.600(c) of this chapter for use as indicated:

(1) See No. 057926 for use as in paragraph (c)(2) of this section.

(2) See No. 000856 for use as in paragraphs (c)(1), (c)(2), and (c)(3) of this section.

(c) *Conditions of use—(1) Dogs—(i) Amount.* 0.025 milligram of butorphanol base activity per pound of body weight (equivalent to 0.5 milliliter per 10 pounds), using 0.5 milligram per milliliter solution.

(ii) *Indications for use.* For the relief of chronic nonproductive cough associated with tracheo-bronchitis, tracheitis, tonsillitis, laryngitis, and pharyngitis associated with inflammatory conditions of the upper respiratory tract.