

§ 522.1372

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by 2.5 milligrams per kilogram administered twice, 24 hours apart.

(2) *Indications.* Treatment of stabilized, class 1, 2, and 3 heartworm disease (asymptomatic to mild, moderate, and severe, respectively) caused by immature (4 month-old, stage L₅) to mature adult infections of *Dirofilaria immitis* in dogs.

(3) *Limitations.* Administer only by deep intramuscular injection in the lumbar muscles (L₃-L₅). Use a 23 gauge 1 inch needle for dogs less than or equal to 10 kilograms (22 pounds) and a 22 gauge 1 1/2 inch needle for dogs greater than 10 kilograms (22 pounds). Use alternate sides with each administration. The drug is contraindicated in dogs with class 4 (very severe) heartworm disease (Caval Syndrome). Not for use in breeding animals and lactating or pregnant bitches. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[60 FR 49340, Sept. 25, 1995]

§ 522.1372 Mepivacaine hydrochloride injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 20 milligrams of mepivacaine hydrochloride.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is intended for use in horses as a local anesthetic for infiltration, nerve block, intra-articular and epidural anesthesia and topical and/or infiltration anesthesia of the laryngeal mucosa prior to ventriculectomy.

(2) It is administered as follows: for nerve block, 3 to 15 milliliters; for epidural anesthesia, 5 to 20 milliliters; for intra-articular anesthesia, 10 to 15 milliliters; for infiltration, as required; for anesthesia of the laryngeal mucosa prior to ventriculectomy, by topical spray, 25 to 40 milliliters, by infiltration, 20 to 50 milliliters.

(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.

[42 FR 5349, Jan. 28, 1977, as amended at 42 FR 36995, July 19, 1977; 55 FR 23076, June 6, 1990]

§ 522.1380 Methocarbamol injection.

(a) *Specifications.* The product is a sterile, pyrogen-free solution, each milliliter containing 100 milligrams of methocarbamol, 0.5 milliliter of polyethylene glycol 300, and water for injection q.s. Its pH is 3.5 to 6.0.

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

(c) *Conditions of use*—(1) *Amount*—(i) *Dogs and cats.* 20 milligrams per pound of body weight for moderate conditions, 25 to 100 milligrams per pound of body weight for severe conditions (tetanus and strychnine poisoning), total cumulative dose not to exceed 150 milligrams per pound of body weight.

(ii) *Horses.* 2 to 10 milligrams per pound of body weight for moderate conditions, 10 to 25 milligrams per pound of body weight for severe conditions (tetanus), additional amounts may be needed to relieve residual effects and to prevent recurrence of symptoms.

(2) *Indications for use.* As an adjunct for treating acute inflammatory and traumatic conditions of the skeletal muscles and to reduce muscular spasms.

(3) *Limitations.* For intravenous use only. For dogs, administer rapidly half the estimated dose, pause until the animal starts to relax, then continue administration to effect. For horses, administer rapidly to effect. Not for horses intended for food use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 79758, Dec. 2, 1980, as amended at 46 FR 18964, Mar. 27, 1981; 67 FR 67521, Nov. 6, 2002]

§ 522.1410 Sterile methylprednisolone acetate suspension.

(a) *Specifications.* Each milliliter of aqueous suspension contains 20 or 40 milligrams of methylprednisolone acetate.¹

(b) *Sponsors.* See Nos. 000009 and 000010 in § 510.600(c) of this chapter.

¹These 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, but may require bioequivalency and safety information.

(c) *Special considerations.* (1) Clinical and experimental data have 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.

(2) Systemic therapy with methylprednisolone acetate, as with other corticoids, is contraindicated in animals with arrested tuberculosis, peptic ulcer, and Cushing's syndrome. The presence of active tuberculosis, diabetes mellitus, osteoporosis, renal insufficiency, predisposition to thrombophlebitis, hypertension, or congestive heart failure necessitates carefully controlled use of corticosteroids. Intrasyovial, intratendinous, or other injections of corticosteroids for local effect are contraindicated in the presence of acute infectious conditions. Exacerbation of pain, further loss of joint motion, with fever and malaise following injection may indicate that the condition has become septic. Appropriate antibacterial therapy should be instituted immediately.

(d) *Conditions of use*—(1) *Amount*—(i) *Intramuscular.* Dosage may be repeated when necessary, as follows: dogs—2 to 40 milligrams (up to 120 milligrams in extremely large breeds or dogs with severe involvement); cats—10 to 20 milligrams; horses—200 milligrams.¹

(ii) *Intrasyovial.* Dosage may be repeated when necessary, as follows: horses—40 to 240 milligrams; dogs—up to 20 milligrams.¹

(2) *Indications for use.* Treatment of inflammation and related disorders in dogs, cats, and horses;¹ treatment of allergic and dermatologic disorders in dogs and cats; and as supportive therapy to antibacterial treatment of severe infections in dogs and cats.

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

[43 FR 59058, Dec. 19, 1978, as amended at 51 FR 741, Jan. 8, 1986; 53 FR 40728, Oct. 18, 1988; 62 FR 35076, June 30, 1997]

§ 522.1451 Moxidectin.

(a) *Specifications.* The drug product consists of two separate vials. One contains 10 percent moxidectin microspheres, and the other contains a vehicle for constitution of the moxidectin microspheres. Each milliliter of constituted, sustained-release suspension contains 3.4 milligrams (mg) of moxidectin.

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

(c) [Reserved]

(d) *Conditions of use; dogs*—(1) *Amount.* 0.17 mg per kilogram body weight (0.0773 mg per pound) as a single subcutaneous injection.

(2) *Indications for use.* For prevention of heartworm disease caused by *Dirofilaria immitis*; for treatment of existing larval and adult hookworm (*Ancylostoma caninum*) and *Uncinaria stenocephala* infections.

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

[66 FR 35756, July 9, 2001, as amended at 67 FR 57944, Sept. 13, 2002]

§ 522.1452 Nalorphine hydrochloride injection.

(a) *Specifications.* Each milliliter of aqueous solution contains 5 milligrams of nalorphine hydrochloride.

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

(c) *Conditions of use*—(1) *Amount.* One milligram per 5 pounds; intravenously, intramuscularly, or subcutaneously.

(2) *Indications for use.* Respiratory and circulatory depression in dogs resulting from overdosage of, or unusual sensitivity to, morphine and certain other narcotics. Not for depression due to any other cause.

(3) *Limitations.* Successive doses of the drug gradually lose their analeptic effect and eventually induce respiratory depression equal to that of opiates. Therefore, do not exceed therapeutic dosage. Do not mix drug with meperidine solutions because the buffer will cause precipitation. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[44 FR 6707, Feb. 2, 1979, as amended at 47 FR 36418, Aug. 20, 1982; 62 FR 63271, Nov. 28, 1997]