

§ 522.1462

21 CFR Ch. I (4-1-03 Edition)

§ 522.1462 Naloxone hydrochloride injection.

(a) *Specifications.* Naloxone hydrochloride injection is an aqueous sterile solution containing 0.4 milligram of naloxone hydrochloride per milliliter.

(b) *Sponsor.* See No. 060951 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used as a narcotic antagonist in dogs.

(2) It is administered by intravenous, intramuscular, or subcutaneous injection at an initial dose of 0.04 milligram per kilogram of body weight. When given intravenously, the dosage may be repeated at 2- to 3-minute intervals as necessary. Onset of action by intramuscular or subcutaneous injection is slightly longer than it is by intravenous injection, and repeated dosages must be administered accordingly.

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

[40 FR 13858, Mar. 27, 1975, as amended at 47 FR 20757, May 14, 1982; 54 FR 32632, Aug. 9, 1989; 63 FR 7701, Feb. 17, 1998]

§ 522.1465 Naltrexone hydrochloride injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 50 milligrams of naltrexone hydrochloride.

(b) *Sponsor.* See 053923 in § 510.600(c) of this chapter.

(c) *Conditions of use in elk and moose—*

(1) *Amount.* 100 milligrams of naltrexone hydrochloride for each milligram of carfentanil citrate administered. One-quarter of the dose should be administered intravenously and three-quarters of the dose should be administered subcutaneously.

(2) *Indications for use.* As an antagonist to carfentanil citrate immobilization in free-ranging or confined elk and moose (*Cervidae*).

(3) *Limitations.* Available data are inadequate to recommend use in pregnant animals. Avoid using during breeding season. Do not use in domestic food-producing animals. Do not use in free-ranging animals for 45 days before or during hunting season. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[62 FR 5320, Feb. 5, 1997]

§ 522.1468 Naproxen for injection.

(a) *Specifications.* The drug is a lyophilized powder which is reconstituted with sterile water for injection to form a 10 percent sterile aqueous solution (100 milligrams per milliliter).

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

(c) *Conditions of use in horses.* (1) *Dosage.* Five milligrams per kilogram of body weight intravenously followed by maintenance oral therapy of 10 milligrams per kilogram of body weight twice daily for up to 14 consecutive days.

(2) *Indications for use.* For the relief of inflammation and associated pain and lameness exhibited with arthritis, as well as myositis and other soft tissue diseases of the musculoskeletal system of the horse.

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

[46 FR 26763, May 15, 1981. Redesignated and amended at 51 FR 24525, July 7, 1986; 61 FR 5507, Feb. 13, 1996]

§ 522.1484 Neomycin sulfate sterile solution.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 50 milligrams of neomycin sulfate (equivalent to 35 milligrams of neomycin base).¹

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

(c) *Conditions of use—*(1) *Amount.* 5 milligrams per pound of body weight daily divided into portions administered every 6 to 8 hours for 3 to 5 days.¹

(2) *Indications for use.* Administer to dogs and cats for the treatment of acute and chronic bacterial infections due to organisms susceptible to neomycin.¹

(3) *Limitations.* For intramuscular or intravenous use only. Neomycin is not for use parenterally in food-producing animals because of prolonged residues in edible tissues. Labeling shall bear an appropriate expiration date. For use by

¹These claims are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter.