§ 522.1222 Ketamine hydrochloride injectable dosage forms.

§ 522.1222a Ketamine.

(a) Specifications. Each milliliter contains ketamine hydrochloride equivalent to 100 milligrams (mg) ketamine base activity.

(b) Sponsors. See Nos. 000010, 059130, 061690, 026637, and 063286 in § 510.600(c) of this chapter.

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

(d) Conditions of use—(1) Cats—(i) Amount. 5 to 15 mg/pound body weight intramuscularly, depending on the effect desired.

(ii) Indications for use. For restraint or as the sole anesthetic agent in diagnostic or minor, brief surgical procedures that do not require skeletal muscle relaxation.

(2) Subhuman primates—(i) Amount. 3 to 15 mg/kilogram body weight intramuscularly, depending upon the species, general condition, and age of the subject.

(ii) Indications for use. For restraint.

§ 522.1222b Ketamine hydrochloride with promazine hydrochloride and aminopentamide hydrogen sulfate injection.

(a) Chemical name. Ketamine hydrochloride, \(\pm\), 2-(o-chlorophenyl)-2-(methylamino) cyclohexanone hydrochloride, with promazine hydrochloride, 10-[3-(dimethylamino) propyl] phenothiazine monohydrochloride, and aminopentamide hydrogen sulfate.

(b) Specifications. The drug is a sterile aqueous solution and each milliliter contains: Ketamine hydrochloride equivalent to 100 milligrams ketamine base activity, 7.5 milligrams of promazine hydrochloride, and 0.0625 milligram of aminopentamide hydrogen sulfate, with 1:10,000 benzethonium chloride.

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

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

(1) It is administered intramuscularly at a recommended dose from 15 to 20 milligrams ketamine base per pound of body weight, depending on the effect desired.

(2) It is used in cats as the sole anesthetic agent for ovariohysterectomy and general surgery.

§ 522.1225 Ketoprofen solution.

(a) Specifications. Each milliliter of sterile aqueous solution contains 100 milligrams of ketoprofen.

(b) Sponsors. See 000856 in 21 CFR 510.600(c) of this chapter.

(c) Conditions of use in horses—(1) Amount. 1.0 milligram per pound of body weight once daily for up to 5 days.

(2) Indications for use. For alleviation of inflammation and pain associated with musculoskeletal disorders in horses.

(3) Limitations. For intravenous use only. Do not use in breeding animals. Effects on fertility, pregnancy, or fetal health have not been determined. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1228 [Reserved]

§ 522.1244 Levamisole phosphate injection.

(a) Specifications. Each milliliter of sterile aqueous solution contains levamisole phosphate equivalent to 13.65 or 182 milligrams of levamisole hydrochloride (13.65 or 18.2 percent).

(b) Sponsors. See Nos. 000061 and 057561 in § 510.600 of this chapter for use of levamisole hydrochloride (13.65 or 18.2 percent).
§ 522.1260 Lincomycin.

(a) Specifications. Each milliliter of solution contains lincomycin hydrochloride monohydrate equivalent to:

(1) 25, 50, 100, or 300 milligrams (mg) lincomycin.

(2) 25, 100, or 300 mg lincomycin.

(3) 300 mg lincomycin.

(4) 100 or 300 mg lincomycin.

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

(1) No. 000039 for use of concentrations in paragraph (a)(1) of this section as in paragraph (e)(2) of this section.

(2) Nos. 058005 and 059130 for use of concentrations in paragraph (a)(2) of this section as in paragraph (e)(2) of this section.

(3) No. 046573 for use of concentration in paragraph (a)(3) of this section as in paragraph (e)(2) of this section.

(4) No. 061623 for use of concentrations in paragraph (a)(4) of this section as in paragraph (e)(2) of this section.

(c) Special considerations. When common labeling for use of the drug in dogs, cats, and swine is included with the drug, all such uses are subject to the labeling requirements of §201.105 of this chapter.

(d) Related tolerances. See §556.360 of this chapter.

(e) Conditions of use. It is used for animals as follows:

1. Dogs and cats—

(1) Amount. 5 mg per pound (lb) of body weight twice daily or 10 mg/lb body weight once daily by intramuscular injection; 5 to 10 mg/lb body weight one or two times daily by slow intravenous injection.

(2) Indications for use. Infections caused by Gram-positive organisms, particularly streptococci and staphylococci.

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

2. Swine—

(1) Amount. 5 mg/lb body weight once daily by intramuscular injection for 3 to 7 days.

(2) Indications for use. Treatment of infectious arthritis and mycoplasma pneumonia.

(3) Limitations. Do not treat within 48 hours of slaughter.


§ 522.1289 Lufenuron suspension.

(a) Specifications. Each milliliter of sterile aqueous suspension contains 10 milligrams of lufenuron.

(b) Sponsor. See No. 058198 in §510.600(c) of this chapter.

(c) [Reserved]

(d) Conditions of use—

1. Cats—

(1) Amount. 10 milligrams per kilogram (4.5 milligrams per pound) of body weight every 6 months, subcutaneously.