

Food and Drug Administration, HHS

§ 522.1244

pound of body weight per day in equally divided doses at 12-hour intervals.

(3) Its label shall bear an appropriate expiration date.

(4) Restricted to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 53 FR 27851, July 25, 1988; 64 FR 403, Jan. 5, 1999]

§ 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, 000074, 000856, 059130, 061690, 064408, and 064847 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.

[67 FR 17283, Apr. 10, 2002]

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

(a) *Chemical name.* Ketamine hydrochloride, (±),-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 hydro-

gen sulfate, with 1:10,000 benzethonium chloride.

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

(d) *Special considerations.* Store in a cool place. Protect from light. Do not use if precipitate appears.

(e) *Conditions of use.* (1) It is used in cats as the sole anesthetic agent for ovariohysterectomy and general surgery.

(2) 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.

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

[40 FR 59342, Dec. 23, 1975, as amended at 42 FR 3838, Jan. 21, 1977; 53 FR 27851, July 25, 1988]

§ 522.1225 Ketoprofen solution.

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

(b) *Sponsor.* 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.

[55 FR 40653, Oct. 4, 1990]

§ 522.1228 [Reserved]

§ 522.1244 Levamisole phosphate injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains levamisole phosphate equivalent to 136.5 or 182 milligrams of levamisole hydrochloride (13.65 or 18.2 percent).

(b) *Sponsor.* See Nos. 000061 and 057561 in § 510.600 of this chapter for use of 13.65 percent injection, and see No. 053501 for use of 13.65 and 18.2 percent injection.

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(c) *Conditions of use*—(1) *Amount*. 2 milliliters per 100 pounds of body weight, subcutaneously in the neck.

(2) *Indications for use*. (i) The 13.65 percent injection is used as an anthelmintic in cattle for treatment of the following parasites: stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*, *Chabertia*), and lungworms (*Dictyoaculus*).

(ii) The 18.2 percent injection is used as an anthelmintic in cattle for treatment of the following parasites: stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*) and lungworms (*Dictyoaculus*).

(3) *Limitations*. Do not administer more than 10 milliliters per site. Cattle that are severely parasitized or maintained under conditions of constant helminth exposure may require retreatment within 2 to 4 weeks after first treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Consult your veterinarian before using in severely debilitated animals or animals under severe stress. Do not administer to cattle within 7 days of slaughter. Do not administer to dairy animals of breeding age.

[43 FR 20489, May 12, 1978, as amended at 43 FR 29289, July 7, 1978; 43 FR 60895, Dec. 29, 1978; 47 FR 10807, Mar. 12, 1982; 62 FR 61625, Nov. 19, 1997; 65 FR 61090, Oct. 16, 2000; 67 FR 63055, Oct. 10, 2002]

§522.1260 **Lincomycin.**

(a) *Specifications*. Each milliliter of solution contains lincomycin hydrochloride monohydrate equivalent to 25, 50, 100, or 300 milligrams (mg) of lincomycin.

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

(1) No. 000009 for uses as in paragraph (e) of this section.

(2) No. 046573 for use 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*—(i) *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.

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

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

(2) *Swine*—(i) *Amount*. 5 mg/lb body weight once daily by intramuscular injection for 3 to 7 days.

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

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

[40 FR 13858, Mar. 27, 1975, as amended at 50 FR 31351, Aug. 2, 1985; 67 FR 34388, May 14, 2002]

§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*—(i) *Amount*. 10 milligrams per kilogram (4.5 milligrams per pound) of body weight every 6 months, subcutaneously.

(ii) *Indications for use*. For use in cats 6 weeks of age and older, for control of flea populations. Lufenuron controls flea populations by preventing the development of flea eggs and does not kill adult fleas. Concurrent use of insecticides may be necessary for adequate control of adult fleas.

(iii) *Limitations*. For subcutaneous use in cats only. The safety of this product in reproducing animals has not been established. Do not use in dogs. Federal law restricts this drug to use by or on the order of a licensed veterinarian.