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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 (Dictyocaulus).
(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 (Dictyocaulus).
(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.

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(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. 000009 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.
(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—(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.

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(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.
(i) **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.

(ii) **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.

[63 FR 29552, June 1, 1998]

§ 522.1290 Luprostiol.

(a) **Specifications.** Each milliliter of solution contains 7.5 milligrams (mg) luprostiol.

(b) **Sponsor.** See No. 051311 in §510.600(c) of this chapter.

(c) **Special considerations.** Labeling shall bear the following statements:

- **Warning:** Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. In the early stages, women may be unaware of their pregnancies. Luprostiol is readily absorbed through the skin and can cause abortion and/or bronchospasms. Direct contact with the skin should therefore be avoided. Accidental spillage on the skin should be washed off immediately with soap and water.

(d) **Conditions of use in horses—(1) Amount.** 7.5 mg by intramuscular injection.

(2) **Indications for use.** For estrus control and termination of pregnancy in mares.

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


§ 522.1315 Maropitant.

(a) **Specifications.** Each milliliter of solution contains 10 milligrams (mg) maropitant as maropitant citrate.

(b) **Sponsor.** See No. 000069 in §510.600(c) of this chapter.

(c) **Conditions of use in dogs—(1) Amount.** Administer 1.0 mg per kilogram body weight by subcutaneous injection once daily for up to 5 consecutive days.

(2) **Indications for use.** For the prevention and treatment of acute vomiting.

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

[72 FR 9243, Mar. 1, 2007]

§ 522.1335 Medetomidine hydrochloride injection.

(a) **Specifications.** Each milliliter of sterile aqueous solution contains 1.0 milligram of medetomidine hydrochloride.

(b) **Sponsor.** See 052483 in §510.600(c) of this chapter.

(c) **Conditions of use—(1) Amount.** 750 micrograms intravenously (IV) or 1,000 micrograms intramuscularly per square meter of body surface. The IV route is more efficacious for dental care.

(2) **Indications for use.** As a sedative and analgesic in dogs over 12 weeks of age to facilitate clinical examinations, clinical procedures, minor surgical procedures not requiring muscle relaxation, and minor dental procedures not requiring intubation. The intravenous route of administration is more efficacious for dental care.

(3) **Limitations.** Do not use in dogs with cardiac disease, respiratory disorders, liver or kidney diseases, dogs in shock, dogs which are severely debilitated, or dogs which are stressed due to extreme heat, cold, or fatigue. Allow agitated dogs to rest quietly before administration. Do not repeat dosing in dogs not responding satisfactorily to treatment. Do not use in breeding or pregnant animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[61 FR 21075, May 9, 1996]