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§ 522.1258  Lidocaine injection with epinephrine.

(a) Specifications. Each milliliter of the drug contains 20 milligrams (2 percent) of lidocaine hydrochloride, 0.01 milligram of epinephrine, with sodium chloride, and with methylparaben as a preservative, in water for injection.

(b) Sponsor. See No. 000402 in §510.600(c) of this chapter.

(c) Conditions of use—

(i) Amount. The drug is administered by injection as a 2 percent solution or diluted with bacteriostatic water for injection to a 0.5 percent solution for local anesthesia of large and small animals, as follows:

(ii) Cattle: Administer 5 milliliters of 2 percent solution with epinephrine by epidural injection. For teat operations and infiltration, inject 0.5 percent solution with epinephrine to effect.

(iii) Dogs: Administer 2 to 10 milliliters of 2 percent solution with epinephrine by caudal injection. Do not give intravascularly. For infiltration, administer 0.5 percent solution with epinephrine to effect.

(iv) Horses: Administer 5 to 10 milliliters of 2 percent solution with epinephrine by cornual nerve block injection. For standing animal, apply slowly and observe individual sensitivity. For infiltration, administer 0.5 percent solution with epinephrine to effect.

(ii) Limitations. (i) The drug is contraindicated in the presence of sepsis in the region of proposed injection, shock and heart block, neurologic disease, spinal deformities, septicemia, and hypertension.

(ii) Do not give intravascularly.

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

§ 522.1260  Lincomycin injection.

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

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

(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:

(i) Dogs and cats—(i) Amount. 5 to 10 milligrams per pound of body weight per day.

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

(iii) Limitations. Administer intramuscularly 10 milligrams per pound of body weight once a day or 5 milligrams per pound of body weight twice daily or intravenously 5 to 10 milligrams per pound of body weight one or two times daily by slow injection. May be diluted with 5 percent glucose in water or normal saline and given as an infusion; as lincomycin hydrochloride monohydrate; for use by or on the order of a licensed veterinarian.

(ii) Swine—(i) Amount. 5 milligrams per pound of body weight per day.
§ 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.

(2) [Reserved]

[63 FR 29552, June 1, 1998]

§ 522.1290 Luprostiol sterile solution.

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

(b) Sponsor. See No. 057926 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—(1) Amount. 7.5 milligrams per mare.

(2) Indications for use. The drug is used in mares for estrus control and termination of pregnancy.

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


§ 522.1335 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) 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. Medetomidine 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—(1) Amount. 7.5 milligrams per mare.

(2) Indications for use. The drug is used in mares for estrus control and termination of pregnancy.

(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]