§ 522.468 Colistimethate sodium powder for injection.

(a) Specifications. Each vial contains colistimethate sodium equivalent to 10 grams colistin activity and mannitol to be reconstituted with 62.5 milliliters sterile saline or sterile water for injection. The resulting solution contains colistimethate sodium equivalent to 133 milligrams per milliliter colistin activity.

(b) Sponsor. See 054771 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) Conditions of use.

(1) 1- to 3-day-old chickens.

(i) Dosage. 0.2 milligram colistin activity per chicken.

(ii) Indications for use. Control of early mortality associated with Escherichia coli organisms susceptible to colistin.

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

(2) [Reserved]


§ 522.480 Corticotropin.

(a) Specifications. Each milliliter of aqueous solution contains 40 or 80 U.S.P. (I.U.) units of repository corticotropin.

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

(1) No. 061623 for use as in paragraphs (c)(1) and (2) of this section.

(2) No. 026637 for use as in paragraph (c)(2) and (3) of this section.

(c) Conditions of use—(1) Dogs—(i) Amount. Administer one unit per pound of body weight by intramuscular injection.

(ii) Indications for use. As a diagnostic aid to test for adrenal dysfunction.

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

(2) Dogs and cats—(i) Amount. Administer one unit per pound of body weight by intramuscular or subcutaneous injection, to be repeated as indicated.

(ii) Indications for use. For stimulation of the adrenal cortex where there is a general deficiency of corticotropin (ACTH).

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

(3) Cattle—(i) Amount. Administer 200 to 600 units by intramuscular or subcutaneous injection as an initial dose, followed by a dose daily or every other day of 200 to 300 units.

(ii) Indications for use. As a therapeutic agent for primary bovine ketosis; and for stimulation of the adrenal cortex where there is a general deficiency of ACTH.

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

[79 FR 16185, Mar. 25, 2014]

§ 522.518 Cupric glycinate injection.

(a) Specifications. Each milliliter (mL) of sterile aqueous suspension contains 200 milligrams of cupric glycinate (equivalent to 60 milligrams of copper).

(b) Sponsor. See No. 049185 in §510.600(c) of this chapter.

(c) Related tolerances. See § 556.169 of this chapter.
Conditions of use in cattle—

(1) 

Amount: Administer by subcutaneous injection either:

(i) 6 mg per kilogram (mg/kg) of body weight, repeated in 48 hours; or

(ii) 8 mg/kg of body weight, as a single dose.

(2) 

Indications for use. For the treatment of bovine respiratory disease (BRD) associated with Mannheimia haemolytica and Pasteurella multocida.

(3) Limitations. Animals intended for human consumption should not be slaughtered within 4 days from the last treatment. Do not use in cattle intended for dairy production. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.535 Desoxycorticosterone.

(a) Specifications. Each milliliter of suspension contains 25 milligrams of desoxycorticosterone pivalate.

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

(c) Conditions of use—

(1) Dogs—

Amount. Dosage requirements are variable and must be individualized on the basis of the response of the patient to therapy. Initial dose of 1 milligram per pound (0.45 kilogram) of body weight every 25 days, intramuscularly. Usual dose is 0.75 to 1.0 milligram per pound of body weight every 21 to 30 days.

(2) [Reserved]

§ 522.536 Detomidine.

(a) Specification. Each milliliter of solution contains 10 milligrams of detomidine hydrochloride.

(b) Sponsor. See No. 052483 in §510.600(c) of this chapter.

(c) Conditions of use in horses—

(1) Amount. For sedation, analgesia, or sedation and analgesia: 20 or 40 micrograms per kilogram (0.2 or 0.4 milliliter per 100 kilogram or 220 pounds) by body weight, depending on depth and duration required. For sedation, administer by intravenous (IV) or intramuscular (IM) injection; for analgesia, administer by IV injection; for both sedation and analgesia, administer by IV injection.

(2) Indication for use. As a sedative and analgesic to facilitate minor surgical and diagnostic procedures in mature horses and yearlings.