

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

(2) [Reserved]

[76 FR 57906, Sept. 19, 2011, as amended at 77 FR 26162, May 3, 2012; 84 FR 39184, Aug. 9, 2019]

§ 522.1020 Gelatin.

(a) *Specifications.* Each 100 milliliters contains 8 grams of gelatin in a 0.85 percent sodium chloride solution.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* The exact dosage to be administered must be determined after evaluating the animal's condition and will vary according to the size of the animal and the degree of shock. A suggested dosage range for small animals such as dogs is 4 to 8 cubic centimeters per pound body weight. The suggested dosage range for large animals such as sheep, calves, cows, or horses is 2 to 4 cubic centimeters per pound of body weight.

(2) *Indications for use.* For use to restore circulatory volume and maintain blood pressure in animals being treated for shock.

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

[79 FR 16189, Mar. 25, 2014]

§ 522.1044 Gentamicin.

(a) *Specifications.* Each milliliter of solution contains gentamicin sulfate equivalent to 5, 50, or 100 milligrams (mg) gentamicin.

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

(1) No. 000061 for use of 5 mg per milliliter (mL) solution in swine as in paragraph (d)(4), 50 mg/mL solution in dogs and cats as in paragraph (d)(1), 50 mg/mL and 100 mg/mL solution in chickens and turkeys as in paragraphs (d)(2) and (d)(3) of this section.

(2) No. 058005 for use of 5 mg/mL solution in swine as in paragraph (d)(4) of this section.

(3) No. 069043 for use of 50 mg/mL solution in dogs as in paragraph (d)(5) of this section.

(4) Nos. 016592 and 061133 for use of 100 mg/mL solution in turkeys as in para-

graph (d)(2) and in chickens as in paragraph (d)(3) of this section.

(c) *Related tolerances.* See § 556.300 of this chapter.

(d) *Conditions of use—(1) Dogs and cats—(i) Amount.* Two milligrams of gentamicin per pound of body weight, twice daily on the first day, once daily thereafter, using a 50 milligram-per-milliliter solution.

(ii) *Indications for use—(a) Dogs.* For the treatment of infections of urinary tract (cystitis, nephritis), respiratory tract (tonsillitis, pneumonia, tracheobronchitis), skin and soft tissue (pyodermatitis, wounds, lacerations, peritonitis).

(b) *Cats.* For the treatment of infections of urinary tract (cystitis, nephritis), respiratory tract (pneumonitis, pneumonia, upper respiratory tract infections), skin and soft tissue (wounds, lacerations, peritonitis), and as supportive therapy for secondary bacterial infections associated with panleucopenia.

(iii) *Limitations.* Administer intramuscularly or subcutaneously. If response is not noted after 7 days, the antibiotic sensitivity of the infecting organism should be retested. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Turkeys—(i) Amount.* Administer subcutaneously in the neck 1 mg of gentamicin per 0.2 mL dose, using the 50- or 100-mg/mL product diluted with sterile saline to a concentration of 5 mg/mL.

(ii) *Indications for use.* As an aid in the prevention of early mortality in 1- to 3-day old turkey poults due to *Ari-zona paracolon* infections susceptible to gentamicin.

(iii) *Limitations.* Injected poults must not be slaughtered for food for at least 9 weeks after treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Chickens—(i) Amount.* Administer subcutaneously in the neck 0.2 mg of gentamicin per 0.2 mL dose, using the 50- or 100-mg/mL product diluted with sterile saline to a concentration of 1.0 mg/mL.

(ii) *Indications for use.* For prevention of early mortality in day-old chickens caused by *Escherichia coli*, *Salmonella*

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typhimurium, and *Pseudomonas aeruginosa* susceptible to gentamicin.

(iii) *Limitations*. Injected chicks must not be slaughtered for food for at least 5 weeks after treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Swine*—(i) *Amount*. Administer 5 mg of gentamicin as a single intramuscular dose using the 5 mg/mL solution.

(ii) *Indications for use*. For treatment of porcine colibacillosis in piglets up to 3 days old caused by strains of *Escherichia coli* sensitive to gentamicin.

(iii) *Limitations*. For single intramuscular dose in pigs up to 3 days of age only. Do not slaughter treated animals for food for at least 40 days following treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(5) *Dogs*—(i) *Amount*. 2 milligrams of gentamicin per pound of body weight, twice daily on the first day, then once daily.

(ii) *Indications for use*. For use in the treatment of urinary tract infections (cystitis) caused by *Proteus mirabilis*, *Escherichia coli*, and *Staphylococcus aureus*.

(iii) *Limitations*. Administer intramuscularly or subcutaneously. If no improvement is seen after 3 days, treatment should be discontinued and the diagnosis reevaluated. Treatment not to exceed 7 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 1942, Jan. 13, 1978, as amended at 48 FR 791, Jan. 7, 1983; 51 FR 15606, Apr. 25, 1986; 52 FR 7832, Mar. 13, 1987; 53 FR 40727, Oct. 18, 1988; 60 FR 29985, June 7, 1995; 61 FR 24441, May 15, 1996; 62 FR 45157, Aug. 26, 1997; 63 FR 59714, Nov. 5, 1998; 63 FR 68182, Dec. 10, 1998; 65 FR 45877, July 26, 2000; 71 FR 76901, Dec. 22, 2006; 78 FR 17597, Mar. 22, 2013; 78 FR 21060, Apr. 9, 2013; 79 FR 21127, Apr. 15, 2014; 81 FR 22524, Apr. 18, 2016; 83 FR 48946, Sept. 28, 2018; 84 FR 8973, Mar. 13, 2019; 88 FR 16547, Mar. 20, 2023]

§ 522.1055 Gleptoferron.

(a) *Specifications*. Each milliliter (mL) contains the equivalent of 200 milligrams of elemental iron as gleptoferron, a complex of ferric hydroxide and dextran glucoheptonic acid.

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(b) *Sponsors*. See No. 013744 in § 510.600(c) of this chapter.

(c) *Conditions of use in swine*—(1) *Indications for use and amounts*. (i) Prevention of anemia due to iron deficiency: Administer 1 mL (200 mg iron) per pig by intramuscular injection on or before 3 days of age.

(ii) Treatment of anemia due to iron deficiency: Administer 1 mL (200 mg iron) per pig by intramuscular injection as soon as signs of deficiency appear.

(2) [Reserved]

[81 FR 59134, Aug. 29, 2016, as amended at 82 FR 11508, Feb. 24, 2017; 82 FR 21690, May 10, 2017]

§ 522.1066 Glycopyrrolate.

(a) *Specifications*. Each milliliter of solution contains 0.2 milligram glycopyrrolate.

(b) *Sponsors*. See Nos. 054771 and 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount*. 5 micrograms per pound of body weight (0.25 milliliter per 10 pounds of body weight) by intravenous, intramuscular, or subcutaneous injection in dogs or by intramuscular injection in cats.

(2) *Indications for use*. As a preanesthetic agent.

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

[71 FR 64451, Nov. 2, 2006, as amended at 78 FR 17597, Mar. 22, 2013; 79 FR 16189, Mar. 25, 2014; 81 FR 17608, Mar. 30, 2016]

§ 522.1077 Gonadorelin.

(a) *Specifications*. Each milliliter (mL) of solution contains:

(1) 43 micrograms (µg) of gonadorelin as gonadorelin acetate;

(2) 100 µg of gonadorelin as gonadorelin acetate;

(3) 50 µg of gonadorelin as gonadorelin diacetate tetrahydrate (equivalent to 43 µg gonadorelin); or

(4) 50 µg of gonadorelin as gonadorelin hydrochloride.

(b) *Sponsors*. See sponsor numbers in § 510.600(c) of this chapter.

(1) No. 000061 for use of the 43-µg/mL product described in paragraph (a)(1) as in paragraphs (e)(1)(i) and (iii) of this section.