Food and Drug Administration, HHS

§ 520.1615 Omeprazole.

(a) Specifications. Each gram of paste contains 0.37 gram omeprazole.

(b) Sponsor. See No. 050604 in § 510.600(c) of this chapter.

(c) Special considerations. When labeled for use as in paragraph (d)(2)(i) of this section, product labeling shall bear: “Federal law restricts this drug to use by or on the order of a licensed veterinarian.”

(d) Conditions of use in horses—(1) Amount—(i) For treatment of gastric ulcers, 1.8 milligrams per pound (mg/lb) of body weight (4 milligrams per kilogram (mg/kg)) once daily for 4 weeks. For prevention of recurrence of gastric ulcers, 0.9 mg/lb of body weight (2 mg/kg) once daily for at least an additional 4 weeks.

(ii) For prevention of gastric ulcers using the premarked syringe, one dose per day for 8 or 28 days. Each dose delivers at least 1 mg/kg of body weight. Horses over 1,200 lb body weight should receive two doses per day.

(2) Indications for use. (i) For treatment and prevention of recurrence of gastric ulcers in horses and foals 4 weeks of age and older.

(ii) For prevention of gastric ulcers in horses.

§ 520.1616 Orbifloxacin tablets.

(a) Specifications. Each tablet contains 5.7, 22.7, or 68 milligrams (mg) orbifloxacin.

(b) Sponsor. See No. 000061 in § 510.600(c) of this chapter.

(c) Conditions of use in dogs and cats—(1) Amount. 2.5 to 7.5 mg per kilogram body weight once daily.

(2) Indications for use. For management of diseases associated with bacteria susceptible to orbifloxacin.

(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

§ 520.1618 Orbifloxacin suspension.

(a) Specifications. Each milliliter of suspension contains 30 milligrams (mg) orbifloxacin.

(b) Sponsor. See No. 000061 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. Federal law prohibits the extralabel use of this drug in food-producing animals.

(d) Conditions of use—(1) Dogs—(i) Amount. 1.1 to 3.4 mg/lb (2.5 to 7.5 mg/kg) of body weight once daily.

(ii) Indications for use. For the treatment of urinary tract infections (cystitis) in dogs caused by susceptible strains of Staphylococcus pseudintermedius, Proteus mirabilis, Escherichia coli, and Enterococcus faecalis and skin and soft tissue infections (wounds and abscesses) in dogs caused by susceptible strains of Staphylococcus pseudintermedius, Staphylococcus aureus, coagulase-positive staphylococci, Pasteurella multocida, Proteus mirabilis, Pseudomonas spp., Klebsiella pneumoniae, E. coli, Enterobacter spp., Citrobacter spp., E. faecalis, β-hemolytic streptococci (Group G), and Streptococcus equisimilis.

(2) Cats—(i) Amount. 3.4 mg/lb (7.5 mg/kg) of body weight once daily.

(3) Limitations. Do not use in horses intended for human consumption.


§ 520.1618 Orbifloxacin suspension.

(a) Specifications. Each milliliter of suspension contains 30 milligrams (mg) orbifloxacin.

(b) Sponsor. See No. 000061 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. Federal law prohibits the extralabel use of this drug in food-producing animals.

(d) Conditions of use—(1) Dogs—(i) Amount. 1.1 to 3.4 mg/lb (2.5 to 7.5 mg/kg) of body weight once daily.

(ii) Indications for use. For the treatment of urinary tract infections (cystitis) in dogs caused by susceptible strains of Staphylococcus pseudintermedius, Proteus mirabilis, Escherichia coli, and Enterococcus faecalis and skin and soft tissue infections (wounds and abscesses) in dogs caused by susceptible strains of Staphylococcus pseudintermedius, Staphylococcus aureus, coagulase-positive staphylococci, Pasteurella multocida, Proteus mirabilis, Pseudomonas spp., Klebsiella pneumoniae, E. coli, Enterobacter spp., Citrobacter spp., E. faecalis, β-hemolytic streptococci (Group G), and Streptococcus equisimilis.

(2) Cats—(i) Amount. 3.4 mg/lb (7.5 mg/kg) of body weight once daily.

(3) Limitations. Do not use in horses intended for human consumption.