

(c) *Conditions of use.* (1) It is used in dogs and cats for the treatment of bacterial pneumonia caused by *Brucella bronchiseptica*, tonsillitis caused by *Streptococcus hemolyticus*, bacterial enteritis caused by *Escherichia coli*, urinary tract infections caused by *Escherichia coli*, and wound infections caused by *Staphylococcus aureus*.¹

(2) The drug is administered orally to dogs and cats at a dosage level of 25-50 milligrams per pound of body weight per day in divided doses at 12-hour intervals. The drug can be used for continuation of compatible antibiotic therapy following parenteral oxytetracycline administration where rapidly attained, sustained antibiotic blood levels are required. The duration of treatment required to obtain favorable response will depend to some extent on the severity and degree of involvement and the susceptibility of the infectious agent. Clinical response to antibiotic therapy usually occurs within 48 to 72 hours. If improvement is not observed within that period, the diagnosis and course of treatment should be reconsidered. To assure adequate treatment, administration of the drug should continue for at least 48 hours following favorable clinical response.¹

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

§ 520.1660c Oxytetracycline hydrochloride tablets/boluses.

(a) *Specifications.* Each tablet or bolus contains 250, 500, or 1,000 milligrams of oxytetracycline hydrochloride.

(b) *Sponsors.* For sponsors in § 510.600(c) of this chapter: See 000010 for use of 500 and 1,000 milligram boluses. See 000069 for use of 250 and 500 milligram tablets.

(c) *Tolerances.* See § 556.500 of this chapter.

(d) *Conditions of use in beef and dairy cattle*—(1)(i) *Amount.* 250 milligrams per 100 pounds of body weight every 12 hours (5 milligrams per pound of body weight daily in two doses).

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(ii) *Indications for use.* For control of bacterial enteritis caused by *Salmonella typhimurium* and *Escherichia coli* (colibacillosis) and bacterial pneumonia (shipping fever complex, pasteurellosis) caused by *Pasteurella multocida*.

(2)(i) *Amount.* 500 milligrams per 100 pound of body weight every 12 hours (10 milligrams per pound of body weight daily in two doses).

(ii) *Indications for use.* For treatment of bacterial enteritis caused by *Salmonella typhimurium* and *Escherichia coli* (colibacillosis) and bacterial pneumonia (shipping fever complex, pasteurellosis) caused by *Pasteurella multocida*.

(3) *Limitations.* Dosage should continue until the animal returns to normal and for 24 hours to 48 hours after symptoms have subsided. Treatment should not exceed 4 consecutive days. Do not exceed 500 milligrams per 100 pounds of body weight every 12 hours (10 milligrams per pound daily). For sponsor 000069: Discontinue treatment 7 days prior to slaughter. Not for use in lactating dairy cattle.

[46 FR 32440, June 23, 1981, as amended at 50 FR 1045, Jan. 9, 1985; 63 FR 70334, Dec. 21, 1998]

§ 520.1660d Oxytetracycline hydrochloride soluble powder.

(a) *Specifications.* The drug is a soluble powder distributed in packets or pails having several concentrations of oxytetracycline hydrochloride (independent of the various net weights) as follows:

(1) Each 18.14 grams of powder contains 1 gram of oxytetracycline hydrochloride (OTC HCl) (packets: 4, 6.4, and 16 oz.).

(2) Each 4.43 grams of powder contains 1 gram of OTC HCl (packets: 4 and 16 oz.).

(3) Each 1.32 grams of powder contains 1 gram of OTC HCl (packets: 2.39, 4.78, and 9.55 oz.; jars: 2.25 lbs.; and pails: 4.5 lbs.).

(4) Each 2.73 grams of powder contains 1 gram of OTC HCl (packets: 2.46 and 9.87 oz; pail: 3.09 lb).

(5) Each 4.2 grams of powder contains 1 gram of OTC HCl (packets: 3.8 and 15.2 oz; pails: 4.74 and 23.7 lb).

(6) Each 1.32 grams of powder contains 1 gram of OTC HCl (packet: 4.78 oz.; pail: 5 lb).

(7) Each 18.1 grams of powder contains 1 gram of OTC HCl (packet: 6.4 oz.; pails: 2 and 5 lb), each 272.2 grams (9.6 oz) of powder contains 204.8 grams of OTC HCl, each 907.2 grams (2 lb) of powder contains 686 grams of OTC HCl, each 2.26 kilograms (5 lb) of powder contains 1,715 grams of OTC HCl.

(8) Each 135.5-gram packet (4.78 ounce) contains 102.4 grams of OTC HCl. Each 677.5-gram packet (23.9 ounce) contains 512 grams of OTC HCl.

(9) Each 2.73 grams of powder contains 1 gram of OTC HCl (packets: 9.87 and 19.75 oz; pails: 3.09 and 5 lb).

(b) *Sponsor*. See sponsor numbers in § 510.600(c) of this chapter as follows:

(1) No. 000069 for use of OTC HCl concentrations in paragraphs (a)(1), (a)(2), and (a)(3) of this section in chickens, turkeys, swine, cattle, sheep, and honey bees.

(2) No. 046573 for use of OTC HCl concentration in paragraph (a)(4) of this section in chickens, turkeys, and swine.

(3) No. 000010 for use of OTC HCl concentration in paragraph (a)(5) of this section in turkeys and chickens.

(4) No. 057561 for use of OTC HCl concentration in paragraph (a)(6) of this section in chickens, turkeys, and swine.

(5) No. 059130 for use of OTC HCl concentration in paragraph (a)(7) of this section in chickens, turkeys, swine, cattle, and sheep.

(6) No. 053389 for use of OTC HCl concentrations in paragraph (a)(8) of this section in chickens, turkeys, swine, cattle, and sheep.

(7) No. 061623 for use of OTC HCl concentration in paragraph (a)(9) of this section in chickens, turkeys, and swine.

(c) *Related tolerances*. See § 556.500 of this chapter.

(d) *Conditions of use*. (1) It is used in drinking water as follows:

(i) *Chickens*—(A)(1) *Amount per gallon*. 200 to 400 milligrams.

(2) *Indications for use*. Control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to oxytetracycline.

(3) *Limitations*. Prepare a fresh solution daily. Administer 7 to 14 days. Not to be used for more than 14 consecutive days. Use as sole source of drinking water. Do not use in birds producing eggs for human consumption.

(B)(1) *Amount per gallon*. 400 to 800 milligrams.

(2) *Indications for use*. Control of chronic respiratory disease (CRD) and air sac infections caused by *Mycoplasma gallisepticum* and *E. coli* susceptible to oxytetracycline; control of fowl cholera caused by *Pasteurella multocida* susceptible to oxytetracycline.

(3) *Limitations*. Prepare a fresh solution daily. Administer 7 to 14 days. Not to be used for more than 14 consecutive days. Use as sole source of drinking water. Do not use in birds producing eggs for human consumption.

(ii) *Turkeys*—(A)(1) *Amount per gallon*. 200 to 400 milligrams.

(2) *Indications for use*. Control of hexamitiasis caused by *Hexamita meleagridis* susceptible to oxytetracycline.

(3) *Limitations*. Prepare a fresh solution daily. Administer 7 to 14 days. Not to be used for more than 14 consecutive days. Use as sole source of drinking water. Do not use in birds producing eggs for human consumption. Withdraw 5 days prior to slaughter those products sponsored by Nos. 000069, and 059130 in § 510.600(c) of this chapter. Withdraw 4 days prior to slaughter those products sponsored by No. 000010. Zero-day withdrawal for those products sponsored by Nos. 046573, 053389, 057561, and 061133.

(B)(1) *Amount per gallon*. 400 milligrams.

(2) *Indications for use*. Control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to oxytetracycline.

(3) *Limitations*. Prepare a fresh solution daily. Administer 7 to 14 days. Not to be used for more than 14 consecutive days. Use as sole source of drinking water. Do not use in birds producing eggs for human consumption. Withdraw 5 days prior to slaughter those products sponsored by Nos. 000069, and 059130 in § 510.600(c) of this chapter. Withdraw 4 days prior to slaughter those products sponsored by No. 000010.

Zero-day withdrawal for those products sponsored by Nos. 046573, 053389, 057561, and 061133.

(C)(1) *Amount.* 25 milligrams per pound of body weight.

(2) *Indications for use.* Growing turkeys. Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to oxytetracycline.

(3) *Limitations.* Prepare a fresh solution daily. Administer 7 to 14 days. Not to be used for more than 14 consecutive days. Use as sole source of drinking water. Do not use in birds producing eggs for human consumption. Withdraw 5 days prior to slaughter those products sponsored by Nos. 000069, and 059130 in § 510.600(c) of this chapter. Withdraw 4 days prior to slaughter those products sponsored by No. 000010. Zero-day withdrawal for those products sponsored by Nos. 046573, 053389, 057561, and 061133.

(iii) *Swine*—(A) *Amount.* 10 milligrams per pound of body weight daily.

(B) *Indications for use.* Control and treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline. For breeding swine: Control and treatment of leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by *Leptospira pomona* susceptible to oxytetracycline.

(C) *Limitations.* Prepare a fresh solution daily. Use as sole source of OTC. Administer up to 14 days; do not use for more than 14 consecutive days; withdraw 5 days prior to slaughter those products sponsored by No. 059130 and zero days those products sponsored by No. 000069. Administer up to 5 days; do not use for more than 5 consecutive days; withdraw zero days prior to slaughter those products sponsored by Nos. 046573, 053389, 057561, and 061133.

(iv) *Calves, beef cattle, and nonlactating dairy cattle*—(A) *Amount.* 10 milligrams per pound of body weight daily.

(B) *Indications for use.* Control and treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia (shipping fever complex) caused by *P. multocida* susceptible to oxytetracycline.

(C) *Limitations.* Prepare a fresh solution daily. Administer up to 14 days. Do not use for more than 14 consecutive days. Use as sole source of oxytetracycline. Do not administer this product with milk or milk replacers. Administer 1 hour before or 2 hours after feeding milk or milk replacers. Withdraw 5 days prior to slaughter. A withdrawal period has not been established for this product in prurinating calves. Do not use in calves to be processed for veal. A milk discard period has not been established for this product in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older.

(v) *Sheep*—(A) *Amount.* 10 milligrams per pound of body weight daily.

(B) *Indications for use.* Control and treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia (shipping fever complex) caused by *P. multocida* susceptible to oxytetracycline.

(C) *Limitations.* Prepare a fresh solution daily. Administer up to 14 days. Do not use for more than 14 consecutive days. Use as sole source of oxytetracycline. Withdraw 5 days prior to slaughter.

(2) It is used in the food of honey bees as follows:

(i) *Amount.* 200 milligrams per colony, administered via either a 1:1 sugar syrup (equal parts of sugar and water weight to weight) or dusting with a powdered sugar mixture.

(ii) *Indications for use.* Control and treatment of American and European foul brood caused by *Bacillus larvae* susceptible to oxytetracycline.

(iii) *Limitations.* The drug is administered in 3 applications of sugar syrup or 3 dustings at 4- to 5-day intervals. The drug should be fed early in the spring or fall and consumed by the bees before main honey flow begins to avoid contamination of production honey. Remove at least 6 weeks prior to main honey flow.

[50 FR 32694, Aug. 14, 1985]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 520.1660d, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.