

**§ 522.1642**

**21 CFR Ch. I (4-1-03 Edition)**

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

[40 FR 13858, Mar. 27, 1975, as amended at 41 FR 32583, Aug. 4, 1976]

**§ 522.1642 Oxymorphone hydrochloride injection.**

(a) *Specifications.* The drug contains 1 or 1.5 milligrams of oxymorphone hydrochloride per milliliter of aqueous solution containing 0.8 percent sodium chloride.

(b) *Sponsor.* See No. 060951 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is a narcotic analgesic, preanesthetic, anesthetic, and substitute anesthetic adjuvant for intramuscular, subcutaneous or intravenous administration to cats and dogs as follows:

| Animal | Body weight (pounds) | Dosage (milligram) |
|--------|----------------------|--------------------|
| Dogs   | 2 to 5               | 0.75               |
|        | 5 to 15              | 0.75-1.5           |
|        | 15 to 30             | 1.5-2.5            |
|        | 30 to 60             | 2.5-4.0            |
|        | Over 60              | 4.0                |
| Cats   | Small                | 0.4-0.75           |
|        | Large                | 0.75-1.5           |

(2) Do not mix with a barbiturate in the same syringe to preclude precipitation.

(3) It tends to depress respiration. Naloxone hydrochloride and other narcotic antagonists are used to counter over-dosing.

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

[40 FR 13858, Mar. 27, 1975, as amended at 63 FR 7701, Feb. 17, 1998]

**§ 522.1660 Oxytetracycline injection.**

(a) *Specifications.* Each milliliter of sterile solution contains 200 milligrams of oxytetracycline base.

(b) *Sponsors.* See 000010, 000069, 011722, 053389, 059130, and 061623 in § 510.600(c) of this chapter.

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

(d) *Conditions of use*—(1) *Beef cattle, dairy cattle, and calves including preruminating (veal) calves.*—(i) *Amount.* 3 to 5 milligrams of oxytetracycline per pound of body weight per day; 5 milligrams per pound of body weight

per day for treatment of anaplasmosis, severe foot-rot, and advanced cases of other indicated diseases; 9 milligrams per pound of body weight as a single dosage where retreatment for anaplasmosis is impractical; 9 milligrams per pound of body weight as single dosage where retreatment of calves and yearlings for bacterial pneumonia is impractical; 9 milligrams per pound of body weight as a single dosage for treatment of infectious bovine keratoconjunctivitis.

(ii) *Indications for use.* Treatment of diseases due to oxytetracycline-susceptible organisms as follows: Pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilis* spp., foot-rot and diphtheria caused by *Fusobacterium necrophorum*, bacterial enteritis (scours) caused by *Escherichia coli*, wooden tongue caused by *Actinobacillus lignieresii*, leptospirosis caused by *Leptospira pomona*, wound infections and acute metritis caused by *Staphylococcus* spp. and *Streptococcus* spp., and infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*. If labeled for use by or on the order of a licensed veterinarian, it may also be used for treatment of anaplasmosis caused by *Anaplasma marginale* and anthrax caused by *Bacillus anthracis*.

(iii) *Limitations.* Administer intramuscularly or intravenously at the 3 to 5 milligrams level, intramuscularly at the 9 milligrams level. Sponsors 000010, 011722, 053389, 055529, and 059130 may also administer subcutaneously at the 3 to 5 milligrams and 9 milligrams levels. Treatment of all diseases should be instituted early and continued for 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 4 consecutive days. Consult your veterinarian if no improvement is noted within 48 hours. Do not inject more than 10 milliliters per site in adult cattle, reducing the volume according to age and body size to 1 to 2 milliliters in small calves. Exceeding the highest recommended dose, administering at recommended levels for more than 4 consecutive days, and/or exceeding 10 milliliters intramuscularly per injection site may result in antibiotic residues beyond the

withdrawal time. Discontinue treatment at least 28 days prior to slaughter. For sponsor 061623: Not for use in lactating dairy cattle. For sponsors 000010, 000069, 011722, 053389, 055529, and 059130: Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food; use subcutaneously with a maximum of 10 milliliters per injection site in adult cattle as well as intramuscularly and intravenously.

(2) *Swine*—(i) *Amount*. 3 to 5 milligrams of oxytetracycline per pound of body weight per day; 9 milligrams per pound of body weight as a single dosage where re-treatment for pneumonia is impractical. Sows: Administer once 3 milligrams of oxytetracycline per pound of body weight, approximately 8 hours before farrowing or immediately after completion of farrowing.

(ii) *Indications for use*. Treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona*. Sows: as an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

(iii) *Limitations*. Administer intramuscularly. Do not inject more than 5 milliliters per site in adult swine. Discontinue treatment at least 28 days prior to slaughter.

[45 FR 16479, Mar. 14, 1980, as amended at 46 FR 20160, Apr. 3, 1981; 46 FR 27913, May 22, 1981; 52 FR 19502, May 26, 1987; 60 FR 14218, Mar. 16, 1995; 60 FR 29755, June 6, 1995; 61 FR 31028, June 19, 1996; 61 FR 36291, July 10, 1996; 62 FR 13825, Mar. 24, 1997; 62 FR 27692, May 21, 1997; 63 FR 52158, Sept. 30, 1998; 64 FR 23187, Apr. 30, 1999; 64 FR 26670, May 17, 1999; 64 FR 42831, Aug. 6, 1999; 66 FR 13235, Mar. 5, 2001; 67 FR 12471, Mar. 19, 2002; 67 FR 47451, July 19, 2002; 67 FR 72366, 72367, Dec. 5, 2002; 67 FR 78357, Dec. 24, 2002; 68 FR 8153, Feb. 20, 2003]

**§ 522.1662 Oxytetracycline hydrochloride implantation or injectable dosage forms.**

**§ 522.1662a Oxytetracycline hydrochloride injection.**

(a)(1) *Specifications*. The drug contains 50 milligrams of oxytetracycline hydrochloride in each milliliter of sterile solution.

(2) *Sponsor*. See No. 000010 in § 510.600(c) of this chapter.

(3) *Conditions of use*. (i) The drug is intended for use in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves for treatment of disease conditions caused by one or more of the following oxytetracycline sensitive pathogens listed as follows: pneumonia and shipping fever complex (*Pasteurella spp.*; *Hemophilis spp.*; *Klebsiella spp.*), bacterial enteritis (scours) (*E. coli*), foot-rot (*Spherophorus necrophorus*), diphtheria (*Spherophorus necrophorus*), wooden tongue (*Actinobacillus lignieresii*), leptospirosis (*Leptospira pomona*), and wound infections; acute metritis; traumatic injury (caused by a variety of bacterial organisms (such as streptococcal and staphylococcal organisms).)

(ii) It is administered by intramuscular injection of 3 to 5 milligrams of oxytetracycline hydrochloride per pound of body weight per day. Leptospirosis, severe foot-rot and severe forms of the indicated diseases should be treated with 5 milligrams per pound of body weight per day. Treatment should be continued for 24 to 48 hours following remission of disease symptoms; however, not to exceed a total of 4 consecutive days. Only 2 milliliters of the drug should be injected per site in case of calves weighing 100 pounds or less and not more than 10 milliliters should be injected per site in adult cattle.

(iii) Discontinue treatment with the drug at least 20 days prior to slaughter of the animal. When administered to animals within 30 days of slaughter, muscle discoloration may necessitate trimming of injection site and surrounding tissues.

(iv) For use only in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves.

(b)(1) *Specifications*. Each milliliter of sterile solution contains 50 or 100 milligrams of oxytetracycline (as oxytetracycline hydrochloride).

(2) *Sponsor*. See 000010 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Beef cattle and nonlactating dairy cattle*—(a) *Amount*. Three to 5 milligrams of oxytetracycline per pound of body weight per day; 5 milligrams per pound of body