

(c) *Conditions of use*—(1) It is used in horses to stimulate infiltration of cellular blood components that subsequently differentiate into fibrous and/or fibrocartilagenous tissue.

(2) The drug is administered by parenteral injection dependent upon the area of response desired. An injection of 1 milliliter will produce a response of approximately 15 square centimeters. Do not inject more than 2 milliliters per injection site. Regardless of the number of injection sites, the total volume used should not exceed 10 milliliters.

(3) Not for use in horses intended for food.

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

[41 FR 27034, July 1, 1976, as amended at 50 FR 40966, Oct. 8, 1985]

**§ 522.1620 Orgotein for injection.**

(a) *Specifications.* Orgotein for injection is packaged in a vial containing 5 milligrams of orgotein and 10 milligrams of sucrose as lyophilized sterile nonpyrogenic powder with directions for dissolving the contents of the vial in 2 milliliters of diluent which is sodium chloride injection, U.S.P.

(b) *Sponsor.* See No. 024991 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Horses.* (i) It is used in the treatment of soft tissue inflammation associated with the musculoskeletal system.

(ii) It is administered by deep intramuscular injection at a dosage level of 5 milligrams every other day for 2 weeks and twice weekly for 2 to 3 more weeks. Severe cases, both acute and chronic, may benefit more from daily therapy initially. Dosage may be continued beyond 5 weeks if satisfactory improvement has not been achieved.

(iii) Not for use in horses intended for food.

(2) *Dogs.* (i) It is used for the relief of inflammation associated with ankylosing spondylitis, spondylosis, and disc disease. When severe nerve damage is present, response will occur much more slowly, if at all.

(ii) It is administered by subcutaneous injection at a dosage level of 5 milligrams every day for 6 days, and there-

after, every other day for 8 days. In less severe conditions, shorter courses of therapy may be indicated.

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

(c) [Reserved]

(d) *Conditions of use*—(1) *Beef cattle, nonlactating 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 re-treatment for anaplasmosis is impractical; 9 milligrams per pound of body weight as single dosage where re-treatment 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 *Haemophilus* 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. Sponsor 000010, 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. Not for use in lactating dairy cattle. For sponsor 000069, 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 42 days prior to slaughter when provided by 000010 and 28 days prior to slaughter when provided by 000069, 053389, 059130, or 061623.

[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]

**§ 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