(b) *Sponsor*. See No. 043264 in § 510.600 of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. The starting dose is 1.0 to 3.0 milligrams per pound (2.2 to 6.7 milligrams per kilogram) once a day.

(2) *Indications for use*. For treatment of pituitary-dependent hyperadrenocorticism. For treatment of hyperadrenocorticism due to adrenocortical tumor.

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

[74 FR 21767, May 11, 2009, as amended at 74 FR 30464, June 26, 2009]

§ 520.2604 Trimeprazine tartrate and prednisolone tablets.

(a) *Specifications*. Each tablet contains: trimeprazine tartrate, 5 milligrams; and prednisolone, 2 milligrams.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is administered orally to dogs for the relief of itching regardless of cause; reduction of inflammation commonly associated with most skin disorders of dogs such as eczema, caused by internal disorders, otitis, and dermatitis, allergic, parasitic, pustular and nonspecific. It is also used in dogs as adjunctive therapy in various cough conditions including treatment of ''kennel cough'' or tracheobronchitis, bronchitis including allergic bronchitis, in tonsillitis, acute upper respiratory infections and coughs of nonspecific origin. The product may also be administered to dogs suffering from acute or chronic bacterial infections, provided the infection is controlled by appropriate antibiotic or chemotherapeutic agents.[1]

(2) The drug is administered orally at an initial dosage level of ½ tablet twice daily to dogs weighing up to 10 pounds, one tablet twice daily to dogs weighing 11 to 20 pounds, two tablets twice daily to dogs weighing 21 to 40 pounds, and three tablets twice daily to dogs weighing over 40 pounds. After 4 days, the dosage is reduced to approximately ½ the initial dosage or to an amount just sufficient to maintain remission of symptoms. Dosages in individual cases may vary and should be adjusted until proper response is obtained.[1]

(3) Do not use the drug in cases of viral infections involving corneal ulceration or dendritic ulceration of the cornea.[1]

(4) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.[1]

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

[40 FR 13838, Mar. 27, 1975, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.2605 Trimeprazine tartrate and prednisolone capsules.

(a) *Specifications*. Each capsule contains 3.75 milligrams of trimeprazine in sustained released form (as the tartrate) and 1 milligram of prednisolone (capsule no. 1) or 7.5 milligrams of trimeprazine in sustained release form (as the tartrate) and 2 milligrams of prednisolone (capsule no. 2).

(b) *Sponsor*. See 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Administer either capsule orally once daily to dogs as follows:

Animal weight (pounds)	Number of capsules per dose	
	Capsule No. 1	Capsule No. 2
Up to 10	1	
11 to 20	2	1
21 to 40	4	2
Over 40	6	3

(2) *Indications for use*. For the relief of itching regardless of cause, reduction of inflammation commonly associated with most skin disorders of dogs such as eczema caused by internal disorders, otitis, and dermatitis (allergic, parasitic, pustular, and nonspecific). It is

[1] These 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.

also used in dogs as adjunctive therapy in various cough conditions including treatment of ''kennel cough'' or tracheobronchitis, bronchitis including allergic bronchitis, tonsillitis, acute upper respiratory infections, and coughs of nonspecific origin. The product may also be administered to dogs suffering from acute or chronic bacterial infections, provided the infection is controlled by appropriate antibiotic or chemotherapeutic agents.

(3) *Limitations.* After 4 days, reduce dosage to one-half the initial dose or to an amount sufficient to maintain remission of symptoms. Dosages in individual cases may vary and should be adjusted until proper response is obtained. Do not use the drug in cases of viral infections involving corneal ulceration or dendritic ulceration of the cornea. Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 19367, Apr. 29, 1983, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.2610 Trimethoprim and sulfadiazine tablets.

(a) *Specifications.* Each tablet contains 30 milligrams (5 milligrams of trimethoprim and 25 milligrams of sulfadiazine), 120 milligrams (20 milligrams of trimethoprim and 100 milligrams of sulfadiazine), 480 milligrams (80 milligrams of trimethoprim and 400 milligrams of sulfadiazine) or 960 milligrams (160 milligrams of trimethoprim and 800 milligrams of sulfadiazine).

(b) *Sponsor.* See Nos. 000061 and 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in dogs where systemic antibacterial action against sensitive organisms is required, either alone or as an adjunct to surgery or debridement with associated infection. The drug is indicated where control of bacterial infection is required during the treatment of acute urinary tract infections, acute bacterial complications of distemper, acute respiratory tract infections, acute alimentary tract infections, wound infections, and abscesses.

(2) The drug is given orally at 30 milligrams per kilogram of body weight per day (14 milligrams per pound per day), or as follows:

Animal body weight (pounds)	Number of tablets
30 MG TABLETS	
2.2	1
4.4	2
6.6	3
8.8	4
120 MG TABLETS	
Up to 9	1
10 to 19	2
20 to 29	3
30 to 40	4
480 MG TABLETS	
30 to 40	1
40 to 60	1½
60 to 80	2
80 to 110	3
Over 110	4

(3) The drug is given once daily. Alternatively, especially in severe infections, the initial dose may be followed by one-half the recommended daily dose every 12 hours. If no improvement is seen in 3 days, discontinue therapy and reevaluate diagnosis.

(4) Administer for 2 to 3 days after symptoms have subsided. Do not treat for more than 14 consecutive days.

(5) During long term treatment, periodic platelet counts and white and red blood cell counts are recommended.

(6) The drug should not be used in patients showing marked liver parenchymal damage or blood dyscrasia, nor in those with a history of sulfonamide sensitivity.

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

[41 FR 3853, Jan. 27, 1976, as amended at 44 FR 32214, June 5, 1979; 46 FR 23231, Apr. 24, 1981; 47 FR 36814, Aug. 24, 1982; 50 FR 9800, Mar. 12, 1985; 50 FR 11852, Mar. 26, 1985; 61 FR 5506, Feb. 13, 1996; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]