

## § 520.2598

Frequently, the drug may be withdrawn after 4 to 5 days, with drug effect continuing after withdrawal.<sup>1</sup>

(3) Do not use in conjunction with organophosphates and/or procaine hydrochloride, because phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.<sup>1</sup>

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.<sup>1</sup>

[40 FR 13838, Mar. 27, 1975, as amended at 50 FR 41489, Oct. 11, 1985]

## § 520.2598 Trilostane.

(a) *Specifications.* Each capsule contains 10, 30, or 60 milligrams (mg) trilostane.

(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

## 21 CFR Ch. I (4–1–11 Edition)

dogs suffering from acute or chronic bacterial infections, provided the infection is controlled by appropriate antibiotic or chemotherapeutic agents.<sup>1</sup>

(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.<sup>1</sup>

(3) Do not use the drug in cases of viral infections involving corneal ulceration or dendritic ulceration of the cornea.<sup>1</sup>

(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.<sup>1</sup>

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.<sup>1</sup>

[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.

<sup>1</sup>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.