Food and Drug Administration, HHS

§ 524.1982 Proparacaine hydrochloride ophthalmic solution.

(a) Specifications. The drug is an aqueous solution containing 0.5 percent proparacaine hydrochloride, 2.45 percent glycerin as a stabilizer, and 0.2 percent chlorobutanol (choral derivative) and 1:10,000 benzalkonium chloride as preservatives.

(b) Sponsor. See No. 053501 in §510.600(c) of this chapter.

(c) Special considerations. The longterm toxicity of proparacaine is unknown. Prolonged use may possibly delay wound healing.

(d) Conditions of use. (1) The drug is indicated for use as a topical ophthalmic anesthetic in animals. It is used as an anesthetic in cauterization of corneal ulcers, removal of foreign bodies and sutures from the cornea, and measurement of intraocular pressure (tonometry) when glaucoma is suspected. Local applications may also be used as an aid in the removal of foreign bodies from the nose and ear canal, as an accessory in the examination and treatment of painful otitis, in minor surgery, and prior to catheterization.

(2) It is administered as follows:
   (i) For removal of sutures: Instill one to two drops 2 or 3 minutes before removal of stitches.
   (ii) For removal of foreign bodies from eye, ear, and nose: For ophthalmic use, instill three to five drops in the eye prior to examination; for otic use, instill five to 10 drops in the ear; for nasal use, instill five to 10 drops in each nostril every 3 minutes for three doses.
   (iii) For tonometry: Instill one to two drops immediately before measurement.
   (iv) As an aid in treatment of otitis: Instill two drops into the ear every 5 minutes for three doses.
   (v) For minor surgery: Instill one or more drops as required.
   (vi) For catheterization: Instill two to three drops with a blunt 20-gauge needle immediately before inserting catheter.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 50 FR 41490, Oct. 11, 1985]

§ 524.2098 Selamectin.

(a) Specifications. Each milliliter contains 60 or 120 milligrams of selamectin.

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

(c) [Reserved]

(d) Conditions of use—(1) Amount. 2.7 milligrams of selamectin, topically, per pound (6 milligrams per kilogram) of body weight.

(2) Indications for use. Kills adult fleas and prevents flea eggs from hatching for 1 month, and it is indicated for the prevention and control of flea infestations (Ctenocephalides felis), prevention of heartworm disease caused by Dirofilaria immitis, and treatment and control of ear mite (Otodectes cynotis) infestations in dogs and cats. Treatment and control of sarcoptic mange (Sarcoptes scabei) and control of tick (Dermacentor variabilis) infestations in dogs. Treatment and control of intestinal hookworm (Ancylostoma tubaeforme) and roundworm (Toxocara cati) infections in cats. For dogs 6 weeks of age and older, and cats 8 weeks of age and older.

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


§ 524.2101 Selenium disulfide suspension.

(a) Specifications. The product contains 0.9-percent weight in weight (w/w) selenium disulfide (1-percent weight in volume (w/v)).

(b) Sponsors. See Nos. 000061, 017135, and 050604 in §510.600(c) of this chapter.

(c) Conditions of use on dogs—(1) Indications for use. For use as a cleansing shampoo and as an agent for removing skin debris associated with dry eczema, seborrhea, and nonspecific dermatoses.

(2) Amount. One to 2 ounces per application.

(3) Limitations. Use carefully around scrotum and eyes, covering scrotum with petrolatum. Allow the shampoo to remain for 5 to 15 minutes before thorough rinsing. Repeat treatment once or twice a week. If conditions persist or if...