§ 524.1600

horses (not for food use). In case of deep or puncture wounds or serious burns, use only as recommended by a veterinarian. If redness, irritation, or swelling persists or increases, discontinue use; consult veterinarian.\(^1\)

\[49 \text{ FR 9417, Mar. 13, 1984}\]

§ 524.1600 Nystatin ophthalmic and topical dosage forms.

\(\)§ 524.1600a Nystatin, neomycin, thiostrepton, and triamcinolone acetonide ointment.

(a) Specifications. Each milliliter of petrolatum base or each gram of vanishing cream base ointment contains: 100,000 units of nystatin; neomycin sulfate equivalent to 2.5 milligrams of neomycin base; 2,500 units of thiostrepton; and 1.0 milligram of triamcinolone acetonide.

(b) Sponsor. See Nos. 000031/000332 (co-sponsors), 000069, 025463, 051259, and 053501 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Amount.

(i) For topical dermatological use: Clean affected areas and remove any encrusted discharge or exudate, and apply sparingly either ointment in a thin film.\(^1\)

(ii) For otic use: Clean ear canal of impacted cerumen, remove any foreign bodies such as grass awns and ticks, and instill three to five drops of petrolatum base ointment. Preliminary use of a local anesthetic may be advisable.\(^1\)

(iii) For infected anal glands and cystic areas: Drain gland or cyst and fill with petrolatum base ointment.\(^1\)

(2) Indications for use. (i) Topically: Use either ointment in dogs and cats for anti-inflammatory, antipruritic, antifungal, and antibacterial treatment of superficial bacterial infections, and for dermatologic disorders characterized by inflammation and dry or exudative dermatitis, particularly associated with bacterial or candidal (Candida albicans) infections.\(^1\)

(ii) Otitis, cysts, and anal gland infections: Use petrolatum base ointment in dogs and cats for the treatment of acute and chronic otitis and interdigital cysts, and in dogs for anal gland infections.\(^1\)


§ 524.1600b Nystatin, neomycin, thiostrepton, and triamcinolone acetonide ophthalmic ointment.

(a) Specifications. Each cubic centimeter of ointment contains: 100,000 units of nystatin, neomycin sulfate equivalent to 2.5 milligrams of neomycin base, 2,500 units of thiostrepton, and 1.0 milligram of triamcinolone acetonide.

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

(c) Conditions of use. (1) The drug is recommended for ophthalmic use as an anti-inflammatory, antipruritic, antifungal (Candida albicans), and antibacterial ointment for local therapy in keratitis and conjunctivitis in cats and dogs and for infectious keratoconjunctivitis (pink eye) in cattle.

(ii) For bovine infectious keratoconjunctivitis: Apply small line of ointment to the affected eye(s) once daily. Treatment may be continued for up to 2 weeks if necessary.

(iii) For bovine infectious keratoconjunctivitis: Apply one drop of ointment to the affected eye(s) once daily. Treatment may be continued for up to 2 weeks if necessary.

(iv) Frequency of administration is dependent on the severity of the condition. For mild inflammations, applications may range from once daily to once a week; for severe conditions, the drug may be applied as often as two to three times daily. Frequency of applications need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.
Food and Drug Administration, HHS

§ 524.1742 N-(Mercaptomethyl) phthalimide S-(0.0-dimethyl phosphorodithioate) emulsifiable liquid.

(a) Specifications. The emulsifiable liquid contains 11.6 percent N-(mercaptopemethyl) phthalimide S-(0.0-dimethyl phosphorodithioate).

(b) Sponsor. See Nos. 011536 and 011716 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Methods of application. Methods of application to control the following conditions on beef cattle:

with adequate ventilation; in case of deep or puncture wounds or serious burns, consult a veterinarian.

§ 524.1662b Oxytetracycline hydrochloride, polymyxin B sulfate ophthalmic ointment.

(a) Specifications. Each gram of the ointment contains oxytetracycline hydrochloride equivalent to 5 milligrams of oxytetracycline and 10,000 units of polymyxin B sulfate.

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

(c) Conditions of use. (1) The drug is used for the prophylaxis and local treatment of superficial ocular infections due to oxytetracycline- and polymyxin-sensitive organisms. These infections include the following: Ocular infections due to streptococci, rickettsiae, E. coli, and A. aerogenes (such as conjunctivitis, keratitis, pink-eye, corneal ulcer, and blepharitis in dogs, cats, cattle, sheep, and horses); ocular infections due to secondary bacterial complications associated with distemper in dogs; and ocular infections due to bacterial inflammatory conditions which may occur secondary to other infectious diseases in dogs, cats, cattle, sheep, and horses.

(2) It is administered topically to the eye two to four times daily.

(3) Allergic reactions may occasionally occur. Treatment should be discontinued if reactions are severe. If new infections due to nonsensitive bacteria or fungi appear during therapy, appropriate measures should be taken.