

§ 524.1443 Miconazole nitrate cream; miconazole nitrate lotion; miconazole nitrate spray.

(a) *Specifications.* (1) The cream contains 23 milligrams of miconazole nitrate (equivalent to 20 milligrams of miconazole base) per gram.

(2) The lotion contains 1.15 percent of miconazole nitrate (equivalent to 1 percent miconazole base).

(3) The spray product consists of a dispensing container, sprayer pump assembly, and lotion which contains 1.15 percent of miconazole nitrate (equivalent to 1-percent miconazole base).

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter for use of cream, lotion, and spray; see No. 051259 in § 510.600(c) of this chapter for use of lotion and spray.

(c) *Conditions of use.* (1) Miconazole nitrate is an antifungal agent for topical treatment of infections in dogs and cats caused by *Microsporum canis*, *Microsporum gypseum*, and *Trichophyton mentagrophytes*.

(2) Apply once daily by rubbing into or spraying a light covering on the infected site and the immediate surrounding vicinity. Continue treatment for 2 to 4 weeks until infection is completely eradicated as determined by appropriate laboratory examination.

(3) Accurate diagnosis of infecting organism is essential. Identify by microscopic examination of a mounting of infected tissue in potassium hydroxide solution or by culture on an appropriate medium.

(4) If no improvement is observed in 2 weeks, reevaluate diagnosis and therapy.

(5) Avoid contact with eyes since irritation may result.

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

[40 FR 13873, Mar. 27, 1975, as amended at 53 FR 26242, July 12, 1988; 62 FR 55161, Oct. 23, 1997; 62 FR 61626, Nov. 19, 1997]

§ 524.1451 Moxidectin.

(a) *Specifications.* Each milliliter contains 5 milligrams of moxidectin (0.5 percent solution).

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.426 of this chapter.

(d) *Conditions of use—(1) Amount.* 0.5 milligrams moxidectin per kilogram (2.2 pounds) of body weight.

(2) *Indications for use.* Beef and non-lactating dairy cattle for treatment and control of internal and external parasites: gastrointestinal roundworms (*Ostertagia ostertagi* (adult and L4, including inhibited larvae), *Haemonchus placei* (adult), *Trichostrongylus axei* (adult and L4), *T. colubriformis* (adult), *Cooperia oncophora* (adult), *C. punctata* (adult), *Bunostomum phlebotomum* (adult), *Oesophagostomum radiatum* (adult), *Nematodirus helvetianus* (adult)); lungworms (*Dictyocaulus viviparus*, adult and L4); cattle grubs (*Hypoderma bovis*, *H. lineatum*); mites (*Chorioptes bovis*, *Psoroptes ovis* (*P. Communis* var. *bovis*)); lice (*Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*, *Damalinia bovis*); and horn flies (*Haematobia irritans*). To control infections and to protect from reinfection with *O. ostertagi* for 28 days after treatment and with *D. viviparus* for 42 days after treatment.

(3) *Limitations.* Apply topically along the top of the back from the withers to the tailhead. Because a withdrawal time for milk has not been established, do not use on female dairy cattle of breeding age. A withdrawal period has not been established for this product on preruminating calves. Do not use on calves to be processed for veal. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[63 FR 14036, Mar. 24, 1998]

§ 524.1465 Mupirocin ointment.

(a) *Specifications.* Each gram contains 20 milligrams of mupirocin.

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

(c) *Conditions of use—(1) Dogs:*

(i) *Indications for use.* Topical treatment of bacterial infections of the skin, including superficial pyoderma, caused by susceptible strains of *Staphylococcus aureus* and *Staphylococcus intermedius*.

(ii) *Limitations.* Apply twice daily. Treatment should not exceed 30 days. Because of potential hazard of nephrotoxicity due to polyethylene glycol content, care should be exercised in treating deep lesions. Safety of

use in pregnant or breeding animals has not been determined. Not for ophthalmic use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[53 FR 39085, Oct. 5, 1988, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 524.1484 Neomycin sulfate ophthalmic and topical dosage forms.

§ 524.1484a Neomycin sulfate ophthalmic ointment.

(a) *Specifications.* Each gram of the ointment contains 5 milligrams of neomycin sulfate equivalent in activity to 3.5 milligrams of neomycin base.

(b) *Sponsor.* See No. 017030 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is intended for use in dogs and cats for the treatment of superficial ocular bacterial infections limited to the conjunctival or the anterior segment of the eye.

(2) The drug is applied four times each day.

(3) The drug is applied by inserting the tip of the tube beneath the lower lid and by expressing a small quantity of ointment into the conjunctival sac. The tip of the tube should not come in contact with the eye surface.

(4) Severe infections should be supplemented by systemic therapy.

(5) Prolonged administration of the drug may permit overgrowth of organisms that are not susceptible to neomycin. If new infections due to bacteria or fungi appear during therapy, appropriate measures should be taken.

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

[40 FR 13873, Mar. 27, 1975, as amended at 44 FR 49666, Aug. 24, 1979]

§ 524.1484b Neomycin sulfate, isoflupredone acetate, tetracaine hydrochloride, and myristyl-gamma-picolinium chloride, topical powder.

(a) *Specifications.* The product contains 5 milligrams of neomycin sulfate, equivalent to 3.5 milligrams of neomycin base, 1 milligram of isoflupredone acetate, 5 milligrams of tetracaine hydrochloride and .2 milligram of

myristyl-gamma-picolinium chloride in each gram of the product in a special adherent powder base.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in horses, dogs, and cats in the treatment or adjunctive therapy of certain ear and skin conditions when such conditions are caused by or associated with neomycin-susceptible organisms and/or allergy. In addition the product is indicated as superficial dressing applied to minor cuts, wounds, lacerations, abrasions, and for postsurgical application where reduction of pain and inflammatory response is deemed desirable. The product may be used as a dusting powder following amputation of tails, claws, and dew-claws and following ear trimming, castrating, and such surgical procedures as ovariohysterectomies. The product may also be used in the treatment of acute otitis externa in dogs, acute moist dermatitis and interdigital dermatitis in dogs.

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

[40 FR 13873, Mar. 27, 1975, as amended at 43 FR 18172, Apr. 28, 1978]

§ 524.1484c Neomycin sulfate, isoflupredone acetate, tetracaine hydrochloride ointment.

(a) *Specifications.* The drug contains 5 milligrams of neomycin sulfate (equivalent to 3.5 milligrams of neomycin base), 1 milligram of isoflupredone acetate, and 5 milligrams of tetracaine hydrochloride in each gram of ointment.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in treating such conditions as acute otitis externa in dogs and to a lesser degree, chronic otitis externa in dogs. It also is effective in treating anal gland infections and moist dermatitis in the dog and is a useful dressing for minor cuts, lacerations, abrasions, and post-surgical therapy in the horse, cat, and dog. It may also be used following amputation of dewclaws, tails and claws, following ear trimming and castrating operations.

(2) In treatment of otitis externa and other inflammatory conditions of the