Food and Drug Administration, HHS

§ 520.1453 Moxidectin and praziquantel gel.

(a) Specifications. Each milliliter of gel contains 20 milligrams (mg) (2.0 percent) moxidectin and 125 mg (12.5 percent) praziquantel.

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

(c) Special considerations. See §500.25 of this chapter.

(2) Indications for use. For the treatment and control of large strongyles: Strongylus vulgaris (adults and L4/L5 ar-terial stages), S. edentatus (adult and tissue stages), Triodontophorus brevicauda (adults), and T. serratus (adults); small strongyles (adults): (Cyathostomum spp., including C. cavitatum and C. paternatum; Cylicocyclus spp., including C. insignis, C. leptostrongylus, C. rossatus, and C. radiatus; Cylicostephanus spp., including C. calicatus, C. longibursatus, and C. minutus; Coronocyclus spp., including C. coronatus, C. labratus, and C. labratus; Gyalocephalus capitatus; and Petrovinema pocuslatus; small strongyles: undifferentiated lumenal larvae; encysted cyathostomes (late L3 and L4 mucosal cyathostome larvae); ascarids: Parascaris equorum (adults and L4 larval stages); pinworms: Oxyurus equi (adults and L4 larval stages); hairworms: Trichostrongylus axei (adults); large-mouth stomach worms: Habronema muscae (adults); horse stomach bots: Gasterophilus intestinalis (2nd and 3rd instars) and G. nasalis (3rd instars); and tapeworms: Anoplocephala perfoliata (adults). One dose also suppresses strongyle egg production for 94 days.

(3) Limitations. For oral use in horses and ponies 6 months of age and older. Not for use in horses and ponies intended for food.

§ 520.1454 Moxidectin solution.

(a) Specifications. Each milliliter (mL) of solution contains 1 milligram (mg) moxidectin.

(b) Sponsor. See No. 000010 in §510.600(c) of this chapter.

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

(d) Special considerations. See §500.25 of this chapter.

(e) Conditions of use in sheep—(1) Amount. Administer 1 mL per 10 pounds body weight (1 mL per 5 kilograms) by mouth.

(2) Indications for use. For the treatment and control of the adult and L4 larval stages of Haemonchus contortus, Teladorsagia circumcincta, T. trifurcata, Trichostrongylus axei, T. colubriformis, T. vitrinus, Cooperia curticei, C. oncophora, Oesophagostomum columbianum, O. venulosum, Nematodirus battus, N. filicollis, and N. spathiger.

(3) Limitations. Sheep must not be slaughtered for human consumption within 7 days of treatment. Because a withholding time in milk has not been established for this product, do not use in female sheep providing milk for human consumption.


§ 520.1468 Naproxen granules.

(a) Specifications. Naproxen granules contain 50 percent naproxen.

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

(c) Conditions of use—(1) Horses. The drug is used for the relief of inflammation and associated pain and lameness exhibited with arthritis, as well as myositis and other soft tissue diseases of the musculoskeletal system of the horse.

(2)(i) For oral maintenance therapy following initial intravenous dosage, administer 10 milligrams naproxen per kilogram of animal body weight twice daily as top dressing in the animal’s feed for up to 14 consecutive days. The initial intravenous dosage is 5 milligrams per kilogram of body weight.

(ii) For oral dosage only, administer 10 milligrams naproxen per kilogram of animal body weight twice daily as a top dressing in the animal’s feed for up to 14 consecutive days.