Food and Drug Administration, HHS

§ 520.1453 Moxidectin and praziquantel gel.

(a) Specifications. Each milliliter of gel contains 20 milligrams (2 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.

(d) Conditions of use in horses and ponies—(1) Amount. Administer by mouth as a single dose: 0.4 mg moxidectin per kilogram and 2.5 mg praziquantel per kilogram (2.2 pounds) body weight.

(2) Indications for use. For the treatment and control of large strongyles: Strongylus vulgaris (adults and L4/L5 arterial stages), S. edentatus (adult and tissue stages), Triodontophorus brevicauda (adults), and T. serratus (adults); small strongyles (adults): Cyathostomum spp., including C. cattinatum and C. pateratum; Cylicocyclus spp., including C. insigne, C. leptostomum, C. nassatus, and C. radiatus; Cylicostephanus spp., including C. calicatus, C. goldi, C. longibursatus, and C. minutus; Coronocyclus spp., including C. coronatus, C. labiatus, and C. labratus; Gyalcephalus capitatus; and Petrovinema pocularis; small strongyles: undifferentiated luminal larvae; encysted cyathostomes (late L3 and L4 mucosal cyathostome larvae); ascarids: Parascaris equorum (adults and L4 larval stages); pinworms: Oxyurus equi (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 84 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.

[68 FR 21956, Apr. 23, 2004; 70 FR 75017, Dec. 19, 2005]

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