

Food and Drug Administration, HHS

§ 520.1452

Consult your veterinarian before administering to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

[49 FR 47831, Dec. 7, 1984, as amended at 51 FR 23415, June 27, 1986; 51 FR 41081, Nov. 13, 1986]

§ 520.1450c Morantel tartrate sustained-release trilaminar cylinder/sheet.

(a) *Specifications.* The drug product consists of a trilaminated, perforated, plastic sheet formed into a cylinder having plastic plugs in its ends. The core lamina contains 19.8 grams of morantel tartrate equivalent to 11.8 grams of morantel base.

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

(c) *Related tolerances.* See § 556.425 of this chapter.

(d) *Conditions of use*—(1) *Amount.* Grazing cattle: Administer 1 cartridge to each animal at the start of the grazing season.

(2) *Indications for use.* For control of the adult stage of the following gastrointestinal nematode infections in weaned calves and yearling cattle weighing a minimum of 200 pounds: *Ostertagia* spp., *Trichostrongylus axei*, *Cooperia* spp., and *Oesophagostomum radiatum*.

(3) *Limitations.* Administer orally with the dosing gun to all cattle that will be grazing the same pasture. Effectiveness of the drug product is dependent upon continuous control of the gastrointestinal parasites for approximately 90 days following administration. Therefore, treated cattle should not be moved to pastures grazed in the same grazing season/calendar year by untreated cattle. Do not administer to cattle within 102 days of slaughter. Consult your veterinarian before administering to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

[56 FR 13396, Apr. 2, 1991]

§ 520.1451 Moxidectin tablets.

(a) *Specifications.* Each tablet contains 30, 68, or 136 micrograms of moxidectin.

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

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount.* 3 micrograms per kilogram (1.36 micrograms per pound) of body weight.

(2) *Indications for use.* To prevent infection by the canine heartworm *Dirofilaria immitis* and the subsequent development of canine heartworm disease.

(3) *Limitations.* Use once-a-month in dogs at 8 weeks of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[62 FR 37713, July 15, 1997]

§ 520.1452 Moxidectin gel.

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

(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.* 0.4 milligram moxidectin per kilogram (2.2 pounds) of 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. catinatum* and *C. pateratum*; *Cylicocyclus* spp., including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. radiatus*; *Cylicocostephanus* spp., including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*; *Coronocyclus* spp., including *C. coronatus*, *C. labiatus*, and *C. labratus*; *Gyalocephalus capitatus*; and *Petrovinema poculatus*; small strongyles: undifferentiated luminal larvae; encysted cyathostomes (late L3 and L4 mucosal cyathostome larvae); ascarids: *Parascaris equorum* (adults and L4 larval stages); pinworms: *Oxyuris equi* (adults and L4 larval stages); hairworms: *Trichostrongylus axei* (adults); large-mouth stomach worms: *Habronema muscae* (adults); and horse stomach bots: *Gasterophilus intestinalis* (2nd and 3rd instars) and *G. nasalis* (3rd