§ 520.666 Dirlotapide.

(a) Specifications. Each milliliter (mL) of solution contains 5 milligrams (mg) dirlotapide.

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

(c) Conditions of use in dogs—(1) Amount. The initial dosage is 0.01 mL/kg (0.0045 mL/lb) body weight for the first 14 days. After the first 14 days of treatment, the dose volume is doubled to 0.02 mL/kg (0.009 mL/lb) body weight for the next 14 days (days 15 to 28 of treatment). Dogs should be weighed monthly and the dose volume adjusted every month, as necessary, to maintain a target percent weight loss until the desired weight is achieved.

(2) Indications for use. For the management of obesity.

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

(2) [Reserved]

[83 FR 8123, Feb. 18, 1998, as amended at 75 FR 10165, March 5, 2010]

§ 520.763a Dithiazanine iodide tablets.

(a) Chemical name. 3-Ethyl-2-[5-(3-ethyl - 2 - benzothiazolinylidene)-1,3-pentadienyl]-benzothiazolium iodide.

(b) Specifications. Dithiazanine iodide tablets contain 10 milligrams, 50 milligrams, 100 milligrams, 200 milligrams of dithiazanine iodide in each tablet.

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

(d) Conditions of use. (1) The tablets are administered orally to dogs immediately after feeding using the following dosage schedule for various parasite infestations:

<table>
<thead>
<tr>
<th>Parasite Infestations</th>
<th>Milligrams per pound of body weight</th>
<th>Length of treatment—days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large roundworms (Toxocara canis, Toxascaris leonina)</td>
<td>10</td>
<td>3–5</td>
</tr>
<tr>
<td>Hookworms (Ancylostoma caninum, Uncinaria stenocephala)</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>Whipworms (Trichuris vulpis)</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>Strongyloides (Strongyloides canis, Strongyloides stercoralis)</td>
<td>10</td>
<td>10–12</td>
</tr>
<tr>
<td>Heartworm microfilariae (Dirofilaria immitis)</td>
<td>3–5</td>
<td>7–10</td>
</tr>
</tbody>
</table>

Note: Treatment with dithiazanine iodide for heartworm microfilariae should follow 6 weeks after therapy for adult worms.

(2) The drug is contraindicated in animals sensitive to dithiazanine iodide and should be used cautiously, if at all, in dogs with reduced renal function.

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

(4) Use for treating dogs for large roundworms, hookworms, whipworms, and strongyloides as provided for in this section has been NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

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(2) Indications for use. For control of large roundworms, *Parascaris equorum*; small strongyles; large strongyles, *Strongylus vulgaris*; and pinworms, *Oxyuris equi*.

(3) Limitations. Administer by drench or mixed with the daily ration as a single dose. Treatment is recommended in spring and fall. In a heavily infested environment, treatment may be repeated every 30 days. Not for use in horses intended for food purposes. Severely debilitated animals should not be wormed except on the advice of a veterinarian. If the drug is for administration by stomach tube, it shall be labeled: "Federal law restricts this drug to use by or on the order of a licensed veterinarian."


§ 520.766 Domperidone.

(a) Specifications. Each milliliter of gel contains 110 milligrams (mg) domperidone.

(b) Sponsor. See No. 043264 in § 510.600 of this chapter.

(c) Conditions of use in horses—(1) Amount. Administer 0.5 mg per pound (mg/lb) (1.1 mg/kilogram (kg)) by mouth once daily starting 10 to 15 days prior to the expected foaling date. Treatment may be continued for up to 5 days after foaling if mares are not producing adequate milk.

(2) Indications for use. For prevention of fescue toxicosis in periparturient mares.

(3) Limitations. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[75 FR 67031, Nov. 1, 2010]

§ 520.784 Doxylamine succinate tablets.

(a) Specifications. The drug is in tablet form and contains doxylamine succinate as the active drug ingredient.

(b) Sponsor. See No. 000061 in § 510.600(c) of this chapter.