§ 522.44 Sterile sodium acetazolamide.

(a) Specifications. Sterile sodium acetazolamide contains acetazolamide sodium complying with United States Pharmacopeia as a sterile powder with directions for reconstituting the product with sterile distilled water to furnish a product having a concentration of 100 milligrams acetazolamide activity per milliliter.

(b) Sponsor. See No. 010042 in §510.600(c) of this chapter.

(c) Conditions of use. (1) It is used as an aid in the treatment of dogs with mild congestive heart failure and for rapid reduction of intraocular pressure.1

1These conditions are NAS/NRC reviewed and deemed effective. Applications for these...
§ 522.52 Alfaxalone.

(a) Specifications. Each milliliter contains 10 milligrams (mg) alfaxalone.

(b) Sponsor. See No. 049480 in §510.600(c) of this chapter.

(c) Conditions of use in cats and dogs—

(1) Amount—(i) Cats—(A) Induction of general anesthesia. Administer by intravenous injection over approximately 60 seconds or until clinical signs show the onset of anesthesia, 2.2 to 9.7 mg/kg for cats that did not receive a preanesthetic or 1.0 to 10.8 mg/kg for cats that received a preanesthetic.

(B) Maintenance of general anesthesia following induction. Administer an intravenous bolus containing 1.1 to 1.3 mg/kg to provide an additional 7 to 8 minutes of anesthesia in preanesthetized cats; a dose containing 1.4 to 1.5 mg/kg provides an additional 3 to 5 minutes anesthesia in unpreanesthetized cats.

(ii) Dogs—(A) Induction of general anesthesia. Administer by intravenous injection over approximately 60 seconds or until clinical signs show the onset of anesthesia, 1.5 to 4.5 mg/kg for dogs that did not receive a preanesthetic or 0.2 to 3.5 mg/kg for dogs that received a preanesthetic.

(B) Maintenance of general anesthesia following induction. Administer an intravenous bolus containing 1.2 to 1.4 mg/kg to provide an additional 6 to 8 minutes of anesthesia in preanesthetized dogs; a dose of 1.5 to 2.2 mg/kg provides an additional 6 to 8 minutes of anesthesia in unpreanesthetized dogs.

(2) Indications for use. For the induction and maintenance of anesthesia and for induction of anesthesia followed by maintenance with an inhalant anesthetic, in dogs and cats.

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

[77 FR 64717, Oct. 23, 2012]

§ 522.56 Amikacin.

(a) Specifications. Each milliliter of solution contains 50 milligrams (mg) of amikacin as amikacin sulfate.

(b) Sponsors. See Nos. 000856 and 000859 in §510.600(c) of this chapter.

(c) Conditions of use in dogs—

(1) Amount. 5 mg/pound (lb) of body weight twice daily by intramuscular or subcutaneous injection.

(2) Indications for use. For the treatment of genitourinary tract infections (cystitis) caused by susceptible strains of Escherichia coli and Proteus spp. and skin and soft tissue infections caused by susceptible strains of Pseudomonas spp. and E. coli.

(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.

[76 FR 17338, Mar. 29, 2011, as amended at 78 FR 17597, Mar. 22, 2013]

§ 522.62 Aminopentamide hydrogen sulfate injection.

(a) Chemical name. 4-(Dimethylamino)-2,2-diphenylvaleramide hydrogen sulfate.

(b) Specifications. It is sterile and each milliliter of aqueous solution contains 0.5 milligram of the drug.

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

(d) Conditions of use. (1) It is intended for use in dogs and cats only for the treatment of vomiting and/or diarrhea, nausea, acute abdominal visceral spasm, pylorospasm, or hypertrophic gastritis.

Note: Not for use in animals with glaucoma because of the occurrence of mydriasis.

(2) Dosage is administered by subcutaneous or intramuscular injection every 8 to 12 hours, as follows:

<table>
<thead>
<tr>
<th>Weight of animal in pounds</th>
<th>Dosage in milligrams</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 10</td>
<td>0.1</td>
</tr>
<tr>
<td>11 to 20</td>
<td>0.2</td>
</tr>
<tr>
<td>21 to 50</td>
<td>0.3</td>
</tr>
<tr>
<td>51 to 100</td>
<td>0.4</td>
</tr>
<tr>
<td>Over 100</td>
<td>0.5</td>
</tr>
</tbody>
</table>