

Food and Drug Administration, HHS

§ 522.2470

§ 514.111 of this chapter, but may require bioequivalency and safety information.

[40 FR 25812, June 19, 1975, as amended at 49 FR 8434, Mar. 7, 1984; 53 FR 23390, June 22, 1988; 53 FR 40728, Oct. 18, 1988; 62 FR 35076, June 30, 1997]

§ 522.2444 Sodium thiopental implantation or injectable dosage forms.

§ 522.2444a Sodium thiopental for injection.

(a) *Specifications.* The drug contains sodium thiopental sterile powder for dilution with sterile water for injection.

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

(c) *Conditions of use.* (1) It is used as an anesthetic for intravenous administration to dogs and cats during short to moderately long surgical and other procedures. It is also used to induce anesthesia in dogs and cats which then have surgical anesthesia maintained by use of a volatile anesthetic.

(2) It is administered as follows:

(i) For brief anesthesia (6 to 10 minutes) a dosage of 6 to 9 milligrams per pound of body weight is suggested.

(ii) To obtain anesthesia of 15 to 25 minutes duration the suggested dosage is 10 to 12 milligrams per pound of body weight.

(iii) Use of a preanesthetic tranquilizer or morphine will decrease the dosage of sodium thiopental required, provide for smoother induction and smoother recovery, and sometimes prolong the recovery period. If morphine is used as a preanesthetic agent the dose of the barbiturate can be reduced as much as 40 to 50 percent. When a tranquilizer is administered the barbiturate dosage can be reduced 10 to 25 percent.

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

§ 522.2444b Sodium thiopental, sodium pentobarbital for injection.

(a) *Specifications.* Each gram of the drug contains 750 milligrams of sodium thiopental and 250 milligrams of sodium pentobarbital sterile powder for dilution with sterile water for injection.

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used as an anesthetic for intravenous administration to dogs and cats during short to moderately long surgical procedures.

(2) It is administered as follows:

(i) For total anesthesia, it is given at approximately 10 to 12 milligrams per pound of body weight over a period of 3.5 to 5 minutes.

(ii) When preanesthetic medication is used, it is important to wait at least an hour before administering thiopental and sodium pentobarbital for injection, and the dosage necessary for anesthesia is reduced. Usually $\frac{1}{2}$ to $\frac{2}{3}$ the normal amount is adequate.

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

[40 FR 13858, Mar. 27, 1975, as amended at 47 FR 14149, Apr. 2, 1982; 66 FR 14073, Mar. 9, 2001; 68 FR 4915, Jan. 31, 2003]

§ 522.2470 Tiletamine hydrochloride and zolazepam hydrochloride for injection.

(a) *Specifications.* Tiletamine hydrochloride and zolazepam hydrochloride for injection when reconstituted with sterile distilled water provides tiletamine hydrochloride and zolazepam hydrochloride equivalent to 50 milligrams of tiletamine base and 50 milligrams of zolazepam base per milliliter of solution.

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

(c) *Conditions of use—*(1) *Indications for use.* It is used for restraint or for anesthesia combined with muscle relaxation in cats and in dogs for restraint and minor procedures of short duration (30 minutes) requiring mild to moderate analgesia.

(2) *Amount.* Expressed as milligrams of the drug combination:

(i) In healthy dogs: An initial intramuscular dosage of 3 to 4.5 milligrams per pound of body weight for diagnostic purposes; 4.5 to 6 milligrams per pound of body weight for minor procedures of short duration such as repair of lacerations and wounds, castrations, and other procedures requiring mild to moderate analgesia. Supplemental doses when required should be less than the initial dose and the