Food and Drug Administration, HHS

§ 522.2662 Xylazine.

(a) Specifications. Each milliliter (mL) of solution contains xylazine hydrochloride equivalent to:

(1) 20 milligrams (mg) xylazine.
(2) 100 mg xylazine.
(3) 300 mg xylazine.

(b) Sponsors. See sponsors in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(1) No. 000010 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.
(2) No. 000010 for use of product described in paragraph (a)(2) of this section as in paragraphs (d)(2), (d)(3)(i), (d)(3)(ii), (d)(3)(iii).
(d)(3)(i)(A), and (d)(3)(iii) of this section.

(3) Nos. 000859 and 061651 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1); and product described in paragraph (a)(2) of this section as in paragraphs (d)(2), (d)(3)(i), (d)(3)(ii)(A), and (d)(3)(iii) of this section.

(4) No. 061690 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1) of this section; product described in paragraph (a)(2) of this section as in paragraphs (d)(2), (d)(3)(i), (d)(3)(ii)(A), and (d)(3)(iii) of this section; and product described in paragraph (a)(3) of this section as in paragraphs (d)(3)(i), (d)(3)(ii)(B), and (d)(3)(iii) of this section.

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

(d) Conditions of use—(1) Dogs and cats—(i) Amount. 0.5 mg/pound (lb) intravenously or 1.0 mg/lb subcutaneously.

(ii) Indications for use. To produce sedation, as an analgesic, and as a preanesthetic to local or general anesthesia.

(2) Horses—(i) Amount. 0.5 mg/lb intravenously or 1.0 mg/lb intramuscularly.

(ii) Indications for use. To produce sedation, as an analgesic, and as a preanesthetic to local or general anesthesia.

(iii) Limitations. Not for use in horses intended for food.

(3) Elk and deer—(i) Amount. Administer intramuscularly, by hand syringe, or by syringe dart, in the heavy muscles of the croup or shoulder as follows:

(A) Elk (Cervus canadensis): 0.25 to 0.5 mg/lb.

(B) Mule deer (Odocoileus hemionus), sika deer (Cervus nippon), and white-tailed deer (Odocoileus virginianus): 1 to 2 mg/lb.

(C) Fallow deer (Dama dama): 2 to 4 mg/lb.

(ii) Indications for use. (A) To produce sedation, as an analgesic, and as a preanesthetic to local anesthesia.

(B) To produce sedation, accompanied by a shorter period of analgesia. May be used to calm and facilitate handling of frac-tious animals for diagnostic procedures, for minor surgical procedures, for therapeutic medication for sedation and relief of pain following injury or surgery, and as a preanesthetic to local anesthetic. At the recommended dosages, can be used in conjunction with local anesthetics, such as procaine or lidocaine.

(iii) Limitations. Do not use in domestic food-producing animals. Do not use in Cervidae less than 15 days before or during the hunting season.


§ 522.2670 Yohimbine injectable.

(a) Specifications. Each milliliter of sterile aqueous solution contains either 2 or 5 milligrams of yohimbine (as hydrochloride).

(b) Sponsor. See 061690 in § 510.600(c) of this chapter for use of 2 milligrams per milliliter solution in dogs.

(1) Amount. 0.05 milligram per pound (0.11 milligram per kilogram) of body weight.

(2) Indications for use. To reverse the effects of xylazine in dogs.

(c) Sponsor. See 053923 in § 510.600(c) of this chapter for use of 5 milligrams per milliliter solution in deer and elk.

(1) Amount. 0.2 to 0.3 milligram per kilogram of body weight.

(2) Indications for use. As an antagonist to xylazine sedation in free ranging or confined members of the family Cervidae (deer and elk).

(3) Limitations. For intravenous use only. Do not use in domestic food-producing animals. Do not use for 30 days before or during hunting season. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 8543, Feb. 16, 1993, as amended at 60 FR 57832, Nov. 22, 1995]

§ 522.2680 Zeranol.

(a) Specifications. Each pellet contains 12, 18, or 20 milligrams (mg) zeranol.

(b) Sponsor. See 000061 in § 510.600(c) of this chapter.