

For Animal Use Only **04944-04**
PropoFlo™ 28 (propofol)

Intravenous Anesthetic Injection for Use in Dogs.

BRIEF SUMMARY OF PRESCRIBING INFORMATION

This summary does not include all the information needed to use PropoFlo™ 28 safely and effectively. See full package insert for complete information.

CAUTION:

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

INDICATIONS:

PropoFlo™ 28 is an intravenous anesthetic injection for use in dogs as follows:

For induction of anesthesia.

For maintenance of general anesthesia by intermittent bolus injections for short procedures.

For induction of general anesthesia where maintenance is provided by inhalant anesthetics.

PropoFlo™ 28 is contraindicated in dogs with a known hypersensitivity to propofol or its components, or when general anesthesia or sedation are contraindicated.

DOSAGE AND ADMINISTRATION (highlights):

Please refer to the complete package insert for full prescribing and administration information before use of this product.

Administer by intravenous injection only. Shake the vial thoroughly before opening. Propofol is a white stable emulsion.

The emulsion should not be mixed with other therapeutic agents prior to administration. No specific preanesthetic is either indicated or contraindicated with propofol. The necessity for, choice of, as well as any necessary reduction of dose for the preanesthetic, is left to the discretion of the veterinarian. The dose of propofol is not affected by anticholinergic premedication.

INDUCTION OF GENERAL ANESTHESIA:

For induction, PropoFlo™ 28 should be titrated against the response of the patient over 60-90 seconds or until clinical signs show the onset of anesthesia. Rapid injection of propofol (≤ 5 seconds) may be associated with an increased incidence of apnea. The use of preanesthetics markedly reduces propofol requirements. The average PropoFlo™ 28 induction dose rates for healthy dogs given propofol alone, or when propofol is preceded by a preanesthetic, are indicated in the table found in the full package insert. This table is based on field study results and is for guidance only. The dose and rate for propofol should be based upon patient response.

MAINTENANCE OF GENERAL ANESTHESIA:

A. Intermittent Propofol Injections:

Anesthesia can be maintained by administering PropoFlo™ 28 in intermittent IV injections.

B. Maintenance by Inhalant Anesthetics:

Due to the rapid metabolism of propofol, additional low doses of propofol, similar to those used for maintenance with propofol, may be required to complete the transition to inhalant maintenance anesthesia.

WARNINGS:

Rapid bolus administration (induction or maintenance) or accidental overdosage of propofol may cause undesirable cardiorespiratory depression including hypotension and oxygen desaturation. Respiratory arrest (apnea) could occur. In cases of respiratory depression, stop drug administration,

establish a patent airway, and initiate assisted or controlled ventilation with pure oxygen. Cardiovascular depression should be treated with plasma expanders, pressor agents, antiarrhythmic agents or other techniques as appropriate for the observed abnormality.

When using propofol, dogs should be continuously monitored and facilities for the maintenance of a patent airway, artificial ventilation, and oxygen supplementation must be immediately available.

HUMAN WARNINGS:

Not for human use. Keep out of the reach of children. Rare cases of self-administration have been reported, including fatalities. PropoFlo™ 28 should be managed to prevent the risk of diversion, through such measures as restriction of access and the use of drug accountability procedures appropriate to the clinical setting. Exercise caution to avoid accidental self-injection. Overdose is likely to cause cardiorespiratory depression (such as hypotension, bradycardia and/or apnea). Remove the individual from the source of exposure and seek medical attention. Respiratory depression should be treated by artificial ventilation and oxygen. Hypersensitivity reactions to propofol, including anaphylaxis, may occur in some individuals who are also allergic to muscle relaxants. Avoid inhalation and direct contact of this product with skin, eyes, and clothes. In case of contact, eyes and skin should be liberally flushed with water for 15 minutes. Consult a physician if irritation persists. The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. For customer service, adverse effects reporting, and/or a copy of the MSDS, call (888) 299-7416.

PRECAUTIONS:

1. Anesthesia effects: Careful monitoring of the patient is necessary when using propofol as a maintenance anesthetic due to the possibility of rapid arousal. Apnea may occur following maintenance doses of propofol. Following induction, additional propofol may be needed to complete the transition to inhalant maintenance anesthesia due to rapid recovery from propofol. Doses administered during the transition to inhalant anesthesia may result in apnea. Propofol has also been used during inhalant maintenance anesthesia to increase anesthetic depth. Propofol used during inhalant maintenance may result in apnea.

2. Physiological effects: Mild hypotension may occur during propofol anesthesia.

3. Preanesthetics: Preanesthetics may increase the anesthesia or sedative effect of propofol and result in more pronounced changes in systolic, diastolic and mean arterial blood pressures.

4. Alpha₂-agonists: PropoFlo™ 28 for maintenance anesthesia was not evaluated in the presence of alpha₂-agonist preanesthesia. The use of an alpha₂-agonist as a preanesthetic may significantly reduce the amount of propofol induction and maintenance anesthetic requirements. Careful patient monitoring during anesthetic induction and maintenance is necessary to avoid anesthetic overdose.

5. Breeding animals: The use of propofol in pregnant and breeding dogs has not been evaluated. Propofol crosses the placenta and, as with other general anesthetic agents, the administration of propofol may be associated with neonatal depression.

6. Neonates and pups: Propofol has not been evaluated in dogs less than 10 weeks of age.

7. Compromised or debilitated dogs: Doses may need adjustment for geriatric or debilitated patients. The administration of propofol to patients with renal failure and/or hepatic failure has not been evaluated. As with other anesthetic agents, caution should be exercised in dogs with cardiac, respiratory, renal or

hepatic impairment, or in hypovolemic or debilitated dogs. Geriatric dogs may require less propofol for induction of anesthesia (see Dosage and Administration).

8. Sighthounds: Propofol induction and maintenance produced satisfactory anesthesia and recoveries in sighthounds. In the clinical study, a total of 27 sighthounds were induced with propofol, 6 of which were maintained on propofol. Induction doses were similar in sighthounds compared to other animals, however, recoveries were delayed.

9. Cardiac arrhythmias: In one study, propofol increased myocardial sensitivity to the development of epinephrine-induced ventricular arrhythmias in a manner similar to other anesthetics. In the PropoFlo field study, transient ventricular arrhythmias associated with propofol were observed in 2 of 145 animals induced and maintained on propofol.

10. Concurrent medication: No significant adverse interactions with commonly used drugs have been observed.

11. Perivascular administration: Perivascular administration does not produce local tissue reaction.

12. Aseptic Handling: PropoFlo™ 28 contains benzyl alcohol as a bacteriostatic preservative. Aseptic technique during handling is recommended. Use of vial contents beyond 28 days may result in microbial contamination causing fever, infection/sepsis, and/or other life-threatening illness. Do not use if contamination is suspected.

13. Cats: PropoFlo™ 28 contains benzyl alcohol which may be toxic to cats.

ADVERSE REACTIONS:

The primary side effect of propofol is respiratory depression as evidenced by tachypnea and apnea. Other less frequent adverse reactions include:

Respiratory: labored breathing

Cardiovascular: hypotension, hypertension, bradycardia, tachycardia, membrane cyanosis, arrhythmias

Musculoskeletal: fasciculations, tenseness, paddling, movements

Central Nervous System: excitation, opisthotonos, seizures, excessive depression
Gastrointestinal: emesis, retching, salivation

HOW SUPPLIED:

PropoFlo™ 28 is supplied in cartons of five-20 mL (200 mg per vial) vials containing 10 mg propofol per mL.

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Product of Sweden

Manufactured by:

ABBOTT LABORATORIES, NORTH CHICAGO, IL 60064, USA

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