

Rapanofal™

(propofol injectable emulsion)
Anesthetic Injection

FREQUENTLY ASKED QUESTIONS

Q: What is RAPANOFAL™ (propofol)?

A: Rapanofal™ (propofol) injection is a sterile, nonpyrogenic emulsion containing 10 mg/mL of propofol suitable for intravenous administration. Propofol is chemically described as 2,6-diisopropylphenol and has a molecular weight of 178.28. Propofol is very slightly soluble in water and is therefore formulated as a white, oil-in-water emulsion. Each mL contains propofol (10 mg), soybean oil (100 mg), glycerol (22.5 mg), egg yolk phospholipid (12 mg) and sodium metabisulfite (0.25 mg), with sodium hydroxide to adjust the pH. The propofol emulsion is isotonic and has a pH of 4.5-6.6.

Q: How is RAPANOFAL™ (propofol) administered?

A: Rapanofal™ (propofol) is administered intravenously.

Q: What are the indications of RAPANOFAL™ (propofol)?

A: Rapanofal™ (propofol) is approved for the anesthetic injection of dogs and cats as follows:

- a) As a single injection to provide general anesthesia for short procedures.
- b) For induction and maintenance of general anesthesia using incremental doses to effect.
- c) For induction of general anesthesia where maintenance is provided by inhalant anesthetics.

Q: Is RAPANOFAL™ (propofol) comparable to Propoflo™ (Zoetis product)?

A: Rapanofal™ (propofol) contains 10mg/mL of propofol and no antimicrobial preservatives. It is approved for use in both dogs and cats.

Q: Can I use a preanesthetic medication before administering RAPANOFAL™ (propofol)?

A: Please consult the package insert that describes the proper use of Rapanofal™ (propofol) in combination with other preanesthetic medications.

Q: What dose of RAPANOFAL™ (propofol) should I use for anesthetic induction and maintenance?

A: Anesthetic induction and maintenance guidelines for use of Rapanofal™ (propofol) in dogs and cats are found in the package insert.

Q: How do I administer RAPANOFAL™ (propofol) for the induction of anesthesia?

A: Use of Rapanofal™ (propofol) for the induction of anesthesia should be titrated against the response of the patient over approximately 60 to 90 seconds or until clinical signs show the onset of anesthesia. If Rapanofal™ (propofol) is injected too slowly (greater than 90 seconds), an inadequate plane of anesthesia can occur. If this occurs, an additional low dose (1.1 mg/kg) of propofol may be administered to facilitate intubation or the transition to inhalant maintenance anesthesia.

Q: What occurs if RAPANOFAL™ (propofol) is over dosed?

A: Rapid administration or accidental overdosage of Rapanofal™ injection may cause neurologic and cardiopulmonary depression. Respiratory arrest (apnea) may be observed.

- a) In cases of respiratory depression, stop drug administration, establish a patent airway, and initiate assisted or controlled ventilation with oxygen.
- b) Cardiovascular depression should be treated with plasma expanders, pressor agents, antiarrhythmic agents or other techniques as appropriate for the observed abnormality.
- c) In feline safety studies using healthy cats and elevated doses of propofol, unexplained decreases in albumin, globulin, and total protein values were noted. Increases in bile acids and triglycerides were also noted and were probably due to the lipid content of the drug formulation. These transient changes were not clinically significant in healthy cats.

Q: How do I need to store RAPANOFAL™ (propofol)?

A: Rapanofal™ (propofol) should be stored between 4-25 degrees Celsius (40-77 degrees Fahrenheit). Do not freeze.

Q: How is RAPANOFAL™ (propofol) supplied?

A: Rapanofal™ (propofol) is supplied in cartons of five-20mL vials.

Q: Once I open a vial of RAPANOFAL™ (propofol), do I need to use it within a certain amount of time?

A: After a Rapanofal™ (propofol) vial is opened, administration should commence promptly and be completed within 6 hours. Any unused product should be discarded within 6 hours.

Q: Does RAPANOFAL™ (propofol) contain preservatives?

A: Rapanofal™ (propofol) is not an antimicrobially preserved product under USP standards.

Q: Why is sodium metabisulfite in RAPANOFAL™ (propofol)?

A: Strict aseptic technique must always be maintained during handling. Rapanofal (propofol injectable emulsion) is a single access parenteral product (single patient infusion vial) that contains sodium metabisulfite (0.25 mg/mL) to retard the rate of growth of microorganisms, for up to 12 hours, in the event of accidental extrinsic contamination. However, propofol injectable emulsion can still support the growth of microorganisms, as it is not an antimicrobially preserved product under USP standards. Do not use if contamination is suspected. Discard unused drug product as directed within the required time limits. There have been reports in which failure to use aseptic technique when handling propofol injectable emulsion was associated with microbial contamination of the product and with fever, infection/sepsis, other life-threatening illness, and/or death.

Q: Can I purchase RAPANOFAL™ (propofol) direct from the manufacturer?

A: While Ivaoes Animal Health does not sell Rapanofal™ (propofol) directly to veterinarians, for questions about product availability, please call 1-844-243-4968.

Q: How do I report an Adverse Event?

A: To report suspected adverse drug events, call 1-888-621-0189.

Q: What occurs if RAPANOFAL™ (propofol) is extravasated?

A: Accidental perivascular injection of Rapanofal (propofol) does not result in irritation or tissue reaction.

- a) Pain on intravenous injection is common in people but is rarely recognized in animals.
 - It does not result in a local inflammatory reaction.
 - It may be more likely when propofol is injected into smaller veins.
- b) Contact of this product with skin, eyes, and clothes should be avoided. If contact occurs, skin and eyes should be liberally flushed with water for 15 minutes. If irritation develops and continues, consult a physician.

For additional information, please refer to the package insert

Additional information can be provided in: Maddison JE, Page SW, Church D. Injectable Anesthetic Agents. Small Animal Clinical Pharmacology. Elsevier Health Sciences, 2008, p 99-101.

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