**Propofol Injectable Emulsion, USP**

**FOR INTRAVENOUS ADMINISTRATION**

Strict aseptic technique must always be maintained during handling. Propofol injectable emulsion is a sterile, ophthalmic solution designed for intravenous use. It contains no preservative.

**Description**

Propofol injectable emulsion is a clear, colorless, sterile, oil-in-water emulsion. It contains propofol, a synthetic lipophilic ester of a long-chain fatty acid. Each milliliter of propofol injectable emulsion contains 100 mg of propofol, 68 mg of soybean oil, 11 mg of lecithin, and 3 mg of monobasic sodium phosphate. The pH is adjusted with sodium hydroxide to a range of 6.5 to 7.5. Under normal conditions, propofol injectable emulsion is stable for 1 year when stored at controlled room temperature (20° to 25°C). Under cold storage conditions (2° to 8°C), propofol injectable emulsion is stable for 2 years.

**Indications**

- Induction of general anesthesia
- Maintenance of general anesthesia
- Sedation in the intensive care unit
- Sedation in the operating room
- Sedation in the recovery room
- Sedation in the postanesthesia care unit

**Contraindications**

- Hypersensitivity to propofol or any component of the propofol injectable emulsion
- Patients undergoing induction of anesthesia with nitrous oxide
- Patients with severe hepatic or renal disease
- Patients with uncontrolled infections

**Warnings and Precautions**

- Propofol injectable emulsion should be given only by intravenous injection because intramuscular injection can cause serious local reactions.

**Adverse Reactions**

- Respiratory depression
- Hypotension
- Bradycardia
- Hypertension
- Allergic reactions

**Important Information**

- Propofol is a rapidly acting anesthetic that produces rapid induction of general anesthesia and a rapid onset of action. The onset of action is approximately 30 seconds after intravenous injection.

**Clinical Pharmacology**

- Propofol is a short-acting, intravenous general anesthetic used for the induction and maintenance of general anesthesia in adults and children.

**Dosage and Administration**

- Propofol injectable emulsion is administered by intravenous injection at a rate of 1 to 5 mg/kg/min or 2 to 10 mg/kg/min, depending on the clinical situation.

**Additional Information**

- Propofol injectable emulsion contains a preservative and should be used within the required time limits.

**References**


**Notes**

- The information provided is for educational purposes only and should not be used as a substitute for medical advice. Always consult a healthcare provider for medical advice specific to your situation.

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**TABLE 1. PREDICTIVE INTERVALS OF EFFECT ON MORTALITY IN ADOLESCENTS**

<table>
<thead>
<tr>
<th>Region</th>
<th>Propofol Dose (mg/kg/min)</th>
<th>Predictive Interval of Effect (%)</th>
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<tbody>
<tr>
<td>0.001</td>
<td>100</td>
<td>5 (95% CI: 2-17)</td>
</tr>
<tr>
<td>0.01</td>
<td>1000</td>
<td>1 (95% CI: 0-7)</td>
</tr>
<tr>
<td>0.1</td>
<td>10000</td>
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**TABLE 2. PREDICTIVE INTERVALS OF EFFECT ON MORTALITY IN ADULTS**

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**Additional Table**

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**Notes**

- The tables above provide predictive intervals of effect on mortality for different regions and propofol doses.

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**Key Points**

- Propofol injectable emulsion is a widely used intravenous anesthetic.
- It is rapidly absorbed into the bloodstream and quickly distributed to tissues.
- Propofol's effects are influenced by factors such as age, weight, and underlying health conditions.

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**References**


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**Figures**

- Figure 1: Predictive intervals of effect on mortality in different regions.
- Figure 2: Predictive intervals of effect on mortality in adults.

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**Tables**

- Table 1: Predictive intervals of effect on mortality in adolescents.
- Table 2: Predictive intervals of effect on mortality in adults.
**Induction of General Anesthesia**

Induction of anesthesia with propofol injectable emulsion should be administered to a patient who is premedicated and who can tolerate general anesthesia. The patient should be monitored at all times, and the inhalation anesthetic agent should be discontinued before administration.

**Induction**

Royal Ottawa Medical Centre (University of Ottawa Faculty of Medicine) and St. Joseph’s Healthcare (McMaster University Faculty of Medicine) have reported that the addition of low-dose propofol injectable emulsion to anesthetic induction may provide a smooth transition from awake to asleep and a reduction in opioid requirements. Propofol injectable emulsion is usually given as a single dose, bolus, or it can be administered at a constant infusion rate.

**Infusion**

**Pediatric Patients**

Propofol injectable emulsion can be administered to pediatric patients using a constant infusion technique. Propofol injectable emulsion can be administered at a rate of 1 to 2 mg/kg/min (6 to 12 mg/kg/h) for 3 to 5 minutes or a slow injection of 40 mg every 10 seconds until induction onset. The tubing and any unused propofol injectable emulsion product must be discarded after 12 hours. If the intermittent bolus dose method is used, increments of propofol injectable emulsion 10 mg (1 mL) or 20 mg (2 mL) can be administered at a rate of 1 to 2 mg/kg/min (6 to 12 mg/kg/h).

**Maintenance**

**Opioid – 50 to 100 mcg/kg/min (see PRECAUTIONS, Pediatric Patients).**

**Nonsteroidal Anti-Inflammatory Agents – 125 to 300 mcg/kg/min (7.5 to 18 mg/kg/h).**

**Pediatric Patients – healthy, from 2 months of age to 16 years of age**

**Hypotension**

**Ventricular Fibrillation**

**Ischemia, Premature Ventricular Contractions, ST Segment**

**Hypoxia**

**Administration of Invasive Monitoring Devices**

To reduce the risk of hypotension, the use of invasive monitoring devices should be minimized. Propofol injectable emulsion has been well-studied in patients with coronary artery disease, but experience in patients with other cardiovascular diseases is limited.

**Special Populations**

**Geriatric Patients**

Propofol injectable emulsion has not been studied in patients with coronary artery disease, but experience in patients with other cardiovascular diseases is limited. Propofol injectable emulsion should be used with caution in geriatric patients, and a lower starting dose (2 to 4 mg/kg) may be needed.

**Menstruating Women**

Propofol injectable emulsion has not been studied in patients with coronary artery disease, but experience in patients with other cardiovascular diseases is limited. Propofol injectable emulsion should be used with caution in men during the menstrual cycle, and a lower starting dose (2 to 4 mg/kg) may be needed.

**Preinduction**

When preinduction is used, propofol injectable emulsion should be administered at a rate of 1 to 2 mg/kg/min (6 to 12 mg/kg/h) for 3 to 5 minutes or a slow injection of 40 mg every 10 seconds until induction onset. The tubing and any unused propofol injectable emulsion product must be discarded after 12 hours. If the intermittent bolus dose method is used, increments of propofol injectable emulsion 10 mg (1 mL) or 20 mg (2 mL) can be administered at a rate of 1 to 2 mg/kg/min (6 to 12 mg/kg/h).

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