



FOR THE USE OF ANAESTHESIOLOGIST ATTACHED TO HOSPITALS, INSTITUTIONS AND NURCING HOMES ONLY.

PROPOFOL

POFOL

10mg/mL (1% w/v)  
Emulsion for I.V. Injection  
General Anesthetic

biocare  
LIFESCIENCES INC



**DESCRIPTION :**  
Propofol injection is a milky-white emulsion filled in 50 ml glass vial.

**FORMULATION :**  
Each mL of emulsion contains:  
Propofol 10mg

**PHARMACOKINETICS :**  
Propofol is well distributed in a three compartment linear model with compartments representing the plasma, rapidly equilibrating tissues, and slowly equilibrating tissues. The first phase is characterized by a very rapid distribution (half life 2 -4 min) followed by rapid elimination (half life 30 - 60 min.) and a slower final phase, representative of redistribution of propofol from poorly perfused tissues. Propofol is extensively distributed and rapidly cleared from the body (total body clearance 1.5-2 lit/min). Clearance occurs by metabolic processes, mainly in the liver, to form inactive conjugates of propofol and its corresponding quinol, which are excreted in urine.

When propofol is used to maintain anaesthesia, the blood concentrations asymptotically approach the steady state value for the given administration rate.

**INDICATIONS :**  
Propofol is a short-acting anaesthetic given intravenously for the induction and maintenance of general anaesthesia. It is also used for sedation in adult patients undergoing diagnostic procedures in those undergoing surgery in conjunction with local or regional anaesthesia, and in ventilated adult patients under intensive care.

**PRECAUTIONS :**  
Propofol should not be given to patients known to be allergic to it. Propofol should be used with caution in patients with hypovalaemia, epilepsy, or lipid metabolism disorders, and in the elderly. Since there have been reports of delayed convulsions associated with ease of propofol it is recommended that special care should be taken when propofol is used for day -care surgery. When used in patients with increased intracranial pressure it should be given slowly to avoid substantial decreases in mean arterial pressure and a resultant decrease in cerebral perfusion pressure. It is also recommended that propofol should not be used with ECT.

**DRUG INTERACTION :**  
The use of propofol with other CNS depressants including those used in premedication, may increase the sedative, anaesthetic and cardio-respiratory depressant effects of propofol. It is recommended that propofol is given after opioids so that the dose of propofol can be carefully titrated against the response. The dosage of propofol should be reduced if used with nitrous oxide or halogenated anaesthetics. Although propofol does not potentiate the effects neuromuscular blockers, bradycardia and asystole have occurred after use of propofol with atracurium or suxamethonium.

**ADVERSE EFFECTS :**  
Adverse effects include pain on injection especially if the injection is into a small vein. Apnoea may be frequent; apnoea lasting longer than 60 seconds has been reported to occur in 12% of patients. Cardiovascular effects include a reduction in blood pressure and bradycardia. There have been reports of convulsions and involuntary movements. Fever has occurred. Discoloration of urine has been reported following prolonged use. Anaphylactic like reactions have been reported, Nausea, vomiting and headache may occur during recovery.

**DOSAGE & ADMINISTRATION :**  
Propofol is available as a 1 or 2% emulsion. The 1% emulsion may be given by intravenous injection or infusion, but the 2% emulsion is for infusion only. Infusions and injections should be prepared using aseptic techniques.

**INTENSIVE CARE UNIT SEDATION :**  
Propofol Injectable Emulsion should be individualized according to the patient's condition and response, blood lipid profile and vital signs. For incubated, mechanically ventilated adult patients, Intensive Care Unit (ICU) sedation should be initiated slowly with a continuous infusion in order to titrate to desired clinical effect and minimize hypotension. When indicated, initiation of sedation should begin at 5 µg/kg/min (0.3 mg/kg/h). the infusion rate should be increased by increments of 5 to 10 µg/kg/min (0.3 - 0.6 mg/kg/h) until the desired level of sedation is achieved. A minimum period of 5 to 10 minutes between adjustments should be allowed for onset of peak drug effect. Most adult patients require maintenance rates of 5 to 50 µg/kg/min (0.3 to 3 mg/kg/h) or higher. Dosages of Propofol should be reduced in patients who have received large dosages of narcotics. Conversely, adequate management of pain may reduce the Propofol Injectable Emulsion dosage requirement with analgesic agents. As with other sedative medications, there is inter patient variability in dosage requirements which may change with time.

EVALUATION OF LEVEL OF SEDATION AND ASSESSMENT OF CNS FUNCTION SHOULD BE CARRIED OUT DAILY THROUGHOUT MAINTENANCE TO DETERMINE THE MINIMUM DOSE OF Propofol INJECTABLE EMULSION REQUIRED FOR SEDATION.

Bolus administration of 10 or 20 mg should be used to rapidly increase in patients where hypotension is not likely to occur. Patients with compromised myocardial function, intravascular volume depletion, or abnormally low vascular tone (e.g. sepsis) may be more susceptible to hypotension.

**INDUCTION OF GENERAL ANAESTHESIA :**  
Healthy Adult Less than 55 years of age: 40mg every 10 seconds until induction onset (1.5 to 2.5mg/kg)  
Elderly, Debilitated or ASA III/IV "Patients: 20 mg every 10 seconds until induction onset (1 to 1.5 mg/kg)  
Cardiac Anaesthesia: 20 mg every 10 seconds until induction onset (0.5 to 1.5 mg/kg)  
Neurosurgical patients: 20 mg every 10 seconds until induction onset (1 to 2 mg/kg)  
Pediatric patients: healthy from 3 years to 16 years of age: 2.5 to 3.5 mg/kg administered over 20-30 seconds.

**MAINTENANCE OF GENERAL ANAESTHESIA :**  
Healthy adult less than 55 years of age: 100 to 200 µg/kg/min (6 to 12 mg/kg/h). (0.1 to 0.2 mg/kg/min)  
Elderly, Debilitated, ASA III/IV patients: 50 to 100 µg/kg/min (3 to 6 mg/kg/h). (0.05 to 0.1 mg/kg/min)

**CARDIAC ANAESTHESIA :**  
Primary Propofol Injectable Emulsion with secondary opioid : 100 - 150 µg/kg/min  
Low dose Propofol Injectable Emulsion with primary opioid: 50 - 100 µg/kg/min  
Neurosurgical patients: 100 - 200 µg/kg/min (6 to 12 mg/kg/h)  
Pediatric patients: healthy from 2 months of age to 16 years of age: 125 to 300 µg/kg/min (7.5 to 18 mg/kg/h)  
Following the first half hour of maintenance, if clinical signs of light anaesthesia are not present the infusion rate should be decreased, intermittent bolus  
Healthy Adults less than 55 years of age: Increments of 20 to 50 mg as needed.

**INITIATION OF MAC SEDATION :**  
Healthy Adult Less than 55 years of age: Slow infusion or slow injection techniques are recommended to avoid apnea or hypotension. Most patients require an infusion of 100 to 150 µg/kg/min (6 to 9 mg/kg/h) for 3 to 5 minutes or a slow injection of 0.5 mg/kg over 3 to 5 minutes followed immediately by a maintenance infusion. Elderly, debilitated, neurosurgical. Or ASA III/IV Patients: Most patients require dosages similar to healthy adults. Rapid boluses are to be avoided.

**MAINTENANCE OF MAC SEDATION :**  
Healthy Adult Less than 55 years of age: A variable rate infusion technique is preferable over an intermittent bolus technique. Most patients require an infusion of 25 to 75 µg/kg/min (1.5 to 4.5 mg/kg/h) or incremental bolus doses of 10 mg or 20 mg. In elderly, debilitated, neurosurgical, or ASA III/IV patients: Most patients require 80% of the usual adult dose. A rapid (single or repeated) bolus dose should not be used. Initiation and maintenance of ICU Sedation in intubated,

mechanically ventilated. Adult patients - Because of the residual effects of previous anaesthetic or sedative agents, in most patients the initial infusion should be 5 µg/kg/min (0.3 mg/kg/h) for at least 5 minutes. Subsequent increments of 5 to 10 µg/kg/min (0.3 to 0.6 mg/kg/h) over 5 to 10 minutes may be used until desired clinical effect is achieved. Maintenance rates of 5 to 50 µg/kg.min (0.3 to 3 mg/kg/h) or higher may be required. Evaluation of clinical effect and assessment of CNS function should be carried out daily throughout maintenance to determine the minimum dose of Propofol required for sedation. The tubing and any unused portions of Propofol should be discarded after 12 hours because Propofol contains no preservatives and is capable of supporting growth of microorganisms.

**COMPATIBILITY AND STABILITY :**  
Propofol Injectable Emulsion should not be mixed with other therapeutic agents prior to administration. Dilution prior to Administration: Propofol Injectable Emulsion is provided as a ready to use formulation. However, should dilution be necessary, it should only be diluted with 5% Dextrose Injection, and it should not be diluted to a concentration less than 2mg/mL because it is an emulsion. In diluted form it has been shown to be more stable when in contact with glass than with plastic (95% potency after 2 hours of running infusion in plastic).

**ADMINISTRATION :**  
Compatibility of Propofol Injectable Emulsion with the co administration of blood/serum/plasma has not been established.

**HANDLING PROCEDURES :**  
Do not use if there is evidence of separation of the phases of the emulsion. Rare cases of self-administration of Propofol Injectable Emulsion by health care professionals have been reported, including some fatalities.

**AVAILABILITY :**  
50 mL USP Type II clear glass vial closed with bromobutyl rubber stopper and plastic flip-off seal (individually boxed) (Box of 6's)

**OVERDOSE AND TREATMENT :**  
It is likely to cause cardiorespiratory depression. Respiratory depression should be treated by artificial ventilation with oxygen. Cardiovascular depression may require repositioning of the patient by raising the patient's legs, increasing the flow rates of intravenous fluids and administering pressor agents and/or anticholinergic agents.

**STORAGE :**  
Store at temperatures not exceeding 30°C.

For suspected adverse drug reaction, report to the FDA: www.fda.gov/ph and BLI: pv@biocarelifesciences.com

D. R. No. : DRP-12521-01

Date of revision of package insert: 27.02.2024

**Caution:**  
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

Distributed by:



**BIOCARE LIFESCIENCES, INC.**  
4th Floor, 393 Goodwill Bldg.,  
Senator Gil Puyat Ave.,  
Brgy. Bel-Air, Makati, Metro Manila

**Manufactured by:**  
Aculife Healthcare Private Limited  
Village: Sachana, Taluka: Viramgam,  
District: Ahmedabad, Gujarat - 382 150. India

**Imported by:**  
**Blue Global (FZE)**  
Unit 1014 Cityland Condominium  
10 Tower 2, H.V. Dela Costa St.,  
Bel-Air, Makati City, Metro Manila