CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
75392

DRAFT FINAL PRINTED LABELING
Propofol Injectable Emulsion 1%
10 mg/ml propofol
Contains a Sulfite
For IV Administration

Propofol is a colorless, odorless, water-soluble liquid with a molecular weight of 426.5. It is composed of 10% propofol, 10% magnesium sulfate, and 10% sodium chloride in water. It is supplied in a 10-mg/ml concentration in a single-use vial. Propofol is a short-acting sedative and anesthetic used for general anesthesia and intravenous induction of anesthesia. It is also used for sedation in the operating room. Propofol is contraindicated in patients with a history of propofol allergy, as it may cause anaphylactic reactions. Propofol is also contraindicated in patients with known hypersensitivity to propofol or its components. Propofol is administered intravenously and is rapidly absorbed into the bloodstream. Peak blood levels are reached within 1-3 minutes after administration. Propofol has a short duration of action, with a recovery time of approximately 30-60 minutes. Propofol is metabolized in the liver and excreted in the urine. Propofol has a low incidence of side effects, with the most common being nausea, vomiting, and headache. However, it has been associated with serious adverse effects, including respiratory depression and cardiac arrhythmias. The administration of propofol should be monitored closely, and appropriate medical equipment and personnel should be available to manage any potential complications.
Clinical studies in humans and animals show that propofol does not suppress the adrenal response to ACTH.

Preliminary findings in patients with normal intracranial pressure indicate that propofol anesthesia produces a decrease in intracranial pressure which may be associated with a concomitant decrease in systemic vascular resistance.

Animals and limited experience in susceptible patients have not indicated any propensity of propofol to induce malignant hyperthermia.

Studies in primates indicate that propofol when used in combination with hypothermia increases cerebrovascular resistance and decreases cerebral blood flow, cerebral metabolic oxygen consumption, and intracranial pressure. Propofol does not affect cerebrovascular reactivity to changes in arterial carbon dioxide tension (see Clinical Trials - Neuroanesthesia).

Pharmacodynamics

The proper use of propofol injectable emulsion requires an understanding of the disposition and elimination characteristics of propofol.

The pharmacokinetics of propofol are well described by a three compartment linear model with compartments representing the plasma, rapidly equilibrating tissues, and slowly equilibrating tissues. Following IV bolus dose, there is a rapid equilibration between the plasma and the highly perfused tissue of the brain, thus accounting for the rapid onset of anesthesia. Plasma levels initially decline rapidly as a result of both rapid distribution and high metabolic clearance. Distribution accounts for about half of the decline following a bolus of propofol.

However, distribution is not constant over time, but decreases as body tissues equilibrate with plasma and become saturated. The rate at which equilibration occurs is a function of the rate and duration of the infusion. When equilibration occurs there is no longer a net transfer of propofol between tissues and plasma.

Discontinuation of the recommended doses of propofol after the maintenance of anesthesia for approximately one hour, or for sedation in the ICU for one day, results in a prompt decrease in blood propofol concentrations and rapid awakening. Larger infusions (10 days of ICU sedation) result in accumulation of significant tissue stores of propofol, such that the reduction in circulating propofol is slowed and the time to awakening is increased.

By daily titration of propofol dosage to achieve only the minimum effective therapeutic concentration, rapid awakening within 10 to 15 minutes will occur even after long-term administration. If, however, higher than necessary infusion levels have been maintained for a long time, propofol will be redistributed from fat and muscle to the plasma and this return of propofol from peripheral tissues will slow recovery.

The figure below illustrates the fall of plasma propofol levels following ICU sedation infusions of various durations.

![Graph showing propofol concentration over time](image)

The large contribution of distribution (about 50%) to the half-life of propofol plasma levels following brief infusions means that after very long infusions (i.e. days) about half the initial dose will remain as plasma levels. Failure to reduce the infusion rate in patients receiving propofol for extended periods may result in excessively high blood concentrations of the drug. Thus, titration to clinical response and daily evaluation of sedation levels are important. Overdose of propofol sedation for ICU sedation, especially of long duration.

Adults: Propofol clearance ranges from 22-50 ml/kg/min (1.5 to 3.4 L/min in 70 kg adults). It is chiefly eliminated by hepatic conjugation to inactive metabolites which are excreted by the kidney. A glomerular creatinine clearance accounts for about 50% of the administered dose. Prophylaxis has a steady state volume of distribution (10-day infusion) approaching 80 L/kg in healthy adults. A difference in pharmacokinetics due to gender has not been observed.

The terminal half-life of propofol after a 10-day infusion is 1 to 3 days.

Geriatrics: With increasing patient age, the dose of propofol needed to achieve a defined anesthetic and pain (dose requirement) decreases. This does not appear to be an age-related change of pharmacodynamics or brain sensitivity, as measured by EEG burst suppression. With increasing patient age, response to infusions higher plasma concentrations occur, which can explain the decrease in anesthetic requirement of elderly patients. The higher plasma levels reflect an age-related decrease in volume of distribution and increased intercompartmental clearance. Lower doses are thus recommended for induction and maintenance of sedoanesthesia in elderly patients (see CLINICAL PharmACology - Individualization of Dose).

Pediatrics: The pharmacokinetics of propofol were studied in 53 children between the ages of 3 and 12 years who received propofol for periods of approximately 1-2 weeks. The observed distribution and clearance of propofol in these children were similar to adults.

Organ Failure: The pharmacokinetics of propofol do not appear to be different in patients with chronic hepatic cirrhosis or chronic renal impairment compared to adults with normal hepatic and renal function. The effects of acute hepatic or renal failure on the pharmacokinetics of propofol have not been studied.

Clinical Trials

Anesthesia and Maintained Anesthesia Care (MAC) Sedation

Propofol was compared to intravenous and inhalational anesthetic or sedative agents in 91 trials involving a total of 5,135 patients. Of these, 3,354 received propofol and comprised the overall safety database for anesthesia and MAC sedation. Fifty-five of these trials, 20 for anesthesia induction and 30 for induction and maintenance of anesthesia or MAC sedation, were carried out in the US or Canada and provided the basis for dosage recommendations and the adverse event profile during anesthesia or MAC sedation.

Pediatric Anesthesia

Propofol was compared to standard anesthetic agents in 12 clinical trials involving 534 patients receiving propofol. Of these, 349 were from US/Canadian clinical trials and comprised the overall safety database for pediatric anesthesia.

<table>
<thead>
<tr>
<th>TABLE 1. PEDIATRIC ANESTHESIA CLINICAL TRIALS</th>
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<tbody>
<tr>
<td>Patients Receiving Propofol Median and (Range)</td>
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<tr>
<td>Induction Dose (mg/kg)</td>
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<tr>
<td>Number of Patients</td>
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<tr>
<td>Induction Doses Dose</td>
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<tr>
<td>Maintenance Dose</td>
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<td>Maintenance Dose</td>
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<td>Maintenance Dose</td>
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*Body weight not recorded for one patient.*

Neuroanesthesia

Propofol was studied in 50 patients undergoing craniotomy for supratentorial tumors in two clinical trials. The mean lesion size (anterior/posterior and lateral) was 31 mm and 32 mm in one trial and 55 mm and 42 mm in the other trial, respectively.

<table>
<thead>
<tr>
<th>TABLE 2. NEUROANESTHESIA CLINICAL TRIALS</th>
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<tr>
<td>Patients Receiving Propofol Median and (Range)</td>
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<tr>
<td>Patient Type</td>
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<tr>
<td>Cranioamy patients</td>
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<td>(9-6.9)</td>
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In ten of these patients, propofol was administered by infusion in a controlled clinical trial to evaluate the effect of propofol on cerebrospinal fluid pressure (CSF). The mean arterial pressure was maintained relative constant over 25 minutes with a change from baseline of 0% ± 5% (mean ± SD), whereas the patient change in cerebrospinal fluid pressure (CSF) was -40% ± 14%. CSF pressure is an indirect measure of intracranial pressure (ICP), which when given by infusion of cerebrospinal fluid or cerebrospinal fluid, in combination with hyperventilation, is capable of decreasing ICP independent of changes in arterial pressure.

Intensive Care Unit (ICU) Sedation

Propofol was compared to benzodiazepines and/or opioids in 14 clinical trials involving a total of 556 ICU patients. Of these, 320 received propofol and comprised the overall safety database for ICU sedation. Six of these studies were carried out in the US or Canada and provided the basis for dosage recommendations and the adverse event profile.

Information from 195 literature reports of propofol used for ICU sedation in over 950 patients and information from the clinical trials are summarized below.

<table>
<thead>
<tr>
<th>TABLE 3. ICU SEDATION CLINICAL TRIALS AND LITERATURE</th>
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<tr>
<td>Patients Receiving Propeofol Median and (Range)</td>
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<tr>
<td>ICU Patient Type</td>
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<tr>
<td>Post-CAIRG</td>
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</tbody>
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| TABLE 2. NEUROMUSCLESTY CLINICAL TRIALS  
| --- | --- | --- | --- |
| Patient Type | No. of Patients | Induction Dose (mg/50 Kg) | Maintenance Dose (mcg/mg) | Maintenance Duration (min)
| Cranberry patients | 50 | 1.26 | 146 | 280 |
| - (2.6-6.9) | - (46-412) | - (46-622) |

In ten of these patients, propofol was administered by infusion in a controlled clinical trial to evaluate the effect of propofol on cerebral blood flow (CBF). The mean arterial pressure was maintained within 25% of the value above and below 140 mm Hg, whereas the percent change in cerebral blood flow (CBF) was 7.5% ± 14%. CBF was not affected by low or high arterial blood pressure levels, or by arterial blood pressure levels, in patients with hypertension. It is possible that increasing DF independent of changes in arterial pressure.

### Intensive Care Unit (ICU) Sedation

Propofol was compared to benzodiazepines and/or opioids in 14 clinical trials involving a total of 530 ICU patients. Of these, 382 received propofol and comprised the overall patient population for statistical analysis. (See Table 3 for details.) These studies were carried out in the US or Canada and provide the basis for dosage recommendations and the adverse event profile.

### Information from VIBEL'S Database of propofol use for ICU sedation in over 1,900 patients and information from the clinical trials are summarized below.

| TABLE 3. ICU SEDATION CLINICAL TRIALS AND LITERATURE  
| --- | --- | --- | --- |
| ICU Patient Type | No. of Patients | Sedation Dose (mg/kg) | Sedation Duration (hours)
| I (necrotizing encephalopathy) | 41 | 11 (0.1-3.6) | 10 (0.6-18)
| II (necrotizing encephalitis) | 334 | 12 (0.6-3) | 18 (0.6-48)
| III (necrotizing encephalopathy) | 231 | 15 (0.6-3) | 18 (0.6-48)
| IV (necrotizing encephalopathy) | 142 | 15 (0.6-3) | 18 (0.6-48)
| V (necrotizing encephalopathy) | 72 | 15 (0.6-3) | 18 (0.6-48)
| VI (necrotizing encephalopathy) | 184 | 15 (0.6-3) | 18 (0.6-48)
| VII (necrotizing encephalopathy) | 76 | 15 (0.6-3) | 18 (0.6-48)

### Anesthesia

Propofol was evaluated in 5 clinical trials conducted in the USA and Canada, involving a total of 569 patients undergoing coronary artery bypass graft (CABG). Of these, 367 patients received propofol. The study database for cardiac anesthesia and provide the basis for dosage recommendations in this population, in conjunction with recommendations in the published literature.

### Individualization of Dosage

**General: Strict Aseptic Technique Must Always Be Maintained During Handling, Propofol Injectable Emulsion in a Single Use Parenteral Product Which Contains Solute Metabolism (0.25 MCG/mL) To Retain the Rate of Growth Among Microorganisms as It IS NOT AN ANTIMICROBIAL PRODUCT UNDER US STANDARDS. Accordingly, Strict Aseptic Technique Must Still Be Adhered To, Do Not Use If Contamination Is Suspected. Discoloration Puncturing As Directed Within The Required Time Limits (See Dosage and Administration, Handling Procedures). There Have Been Reports of Infections Which Failure to Use Aseptic Technique When Handling Propofol Injectable Emulsion Was Associated with Microbial Contamination of the Product and With Fever, Infection/Inflammation, Other Life-Threatening Illness, and Death.**

Propofol blood concentrations at steady state are generally proportional to infusion rates, especially in individual patients. Undesirable effects such as cardiac depression and respiratory depression are likely to occur at higher blood concentrations, which must be below doses or rapid increases in the infusion rate. An adequate interval (3 to 5 minutes) must be allowed between clinical dose adjustments in order to assess drug effects.

When administering propofol by intravenous, syringe pumps or volumetric pumps are recommended to provide controlled infusion rates. When infusing propofol to patients undergoing cardiac anesthesia, infusion pumps may be used if mechanical pumps are impractical.

### Changes in Vital Signs

Changes in vital signs are indicated by pulse rate, blood pressure, sweating, and/or wearing to indicate a response to surgical stimulation or tightening of anesthesia by control of the administration of propofol 25 mg (2.5 mg/mL) to 50 mg (5 mg/mL) incremental boluses and/or by increasing the infusion rate.

For minor surgical procedures (e.g., body surface), nitrous oxide (60%–70%) can be combined with a variable rate propofol infusion to provide satisfactory anesthesia. With more stimulating surgical procedures (e.g., intra-abdominal), or for supplementation with nitrous oxide is not provided, administration of analgesic and/or opioids should be increased in order to provide adequate anesthesia.

### Sedation

Sedation rates should always be titrated downward in the absence of clinical signs of light anesthesia until a mild response to surgical stimulation is obtained. In order to avoid administration of propofol at rates higher than those clinically necessary. Generally, rates of 50 to 100 mcg/mg in adults should be achieved during maintenance in order to optimize recovery times.

Other drugs that cause CNS depression (hypnotics, sedatives, hypnotics, and opioids) can increase CNS depression induced by propofol. Hypnotic premedication (0.1 mg) with propofol at 30 mg/kg with oxygen has been shown to decrease the necessary propofol injection maintenance rate and therapeutic blood concentrations when compared to non-narcotic (loxapine) predominance.

### Sedation of General Anesthesia

**Adult Patients:** Most adult patients under 55 years of age and classified ASA II require 2 to 2.5 mg/kg of propofol for induction when uncomplicated or when premedicated with oral benzodiazepines or intramuscular opioids. For induction, propofol should be titrated (approximately 40 mg every 10 seconds) against the response of the patient until the clinical signs show the onset of anesthesia. As with other sedative/hypnotic agents, the amount of intravenous opioid and/or benzodiazepine per patient on the induction dose of propofol.

**Elderly, Debilitated, or ASA III/IV Patients:** It is important to be familiar with the intravenous use of propofol before treating elderly, debilitated, or ASA III/IV patients. Due to the reduced clearance and higher blood concentrations, most of these patients require approximately 1.5 to 2.5 mg/kg (approximately 20 microliters per kg) of propofol for induction of anesthesia according to their condition and response. A rapid bolus should be used as the will increase the likelihood of undesirable cardiovascular depression including hypotension, apnea, arrhythmia, and/or oxygen desaturation (see DOSAGE AND ADMINISTRATION).

### Neonatal Patients

Sedation induction is recommended using boluses of 20 mg every 10 seconds. Bolus induction or boluses of propofol for induction of anesthesia limited to clinical conditions, will generally result in reduced induction dosage requirements (1 to 2 mg/kg). (See PRECAUTIONS and DOSAGE AND ADMINISTRATION)

### Cardiac Anesthesia

Propofol has been well studied in patients with coronary artery disease, but experience in patients with hemodynamically significant valvular or congenital heart disease is limited. As with other patients who suffer an increase in blood pressure that is secondary to decreases in preload (ventricular filling volume at the beginning and afterload (arterial resistance at the beginning of the beat) heart rate and effective site concentrations achieved. These concentrations depend on the blood pressure and the duration of anesthesia and to minimize infusion rate.

In addition, lower heart rates are observed during maintenance with propofol, possibly due to reduction in the sympathetic activity and/or reduction of the baroreflexes. Therefore, antihypertensives should be administered when increases in vasal tone are anticipated.

As with other anesthetic agents, propofol reduces myocardial oxygen consumption. Further studies are needed to confirm and delineate the extent of these effects on the myocardium and the coronary vasmotor system.

### Muscle Relaxation

Muscle paralysis (0.1 mg/kg) with nitrous oxide 67% is oxygen has been shown to decrease the necessary propofol maintenance infusion rates and therapeutic blood concentrations when compared to non-narcotic (lorazepam) predominance.
TABLE 4. CARDIAC ANESTHESIA TECHNIQUES

<table>
<thead>
<tr>
<th>Primary Agent</th>
<th>Rate (intravenous injection)</th>
<th>Secondary Agent/Rate</th>
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<tbody>
<tr>
<td>Propofol</td>
<td>25 mcg/kg/min</td>
<td>(Following Induction with Primary Agent)</td>
</tr>
<tr>
<td></td>
<td>0.5-1.5 mcg/kg/min over 30 sec</td>
<td>(DPIVIVI: 0.037 mcg/kg/min no bolus)</td>
</tr>
<tr>
<td>Maintenance</td>
<td>100-150 mcg/kg/min</td>
<td>(If titrated to Clinical Response)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(DPIVIVI: 50-100 mcg/kg/min no bolus)</td>
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</tbody>
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*Propofol is defined, in terms of fatal toxic effects, i.e.: 1 mg/kg of total dose, 1 mg/kg of maintenance dose, or 0.5 mg/kg of bolus dose. Care should be taken to avoid anxiouls with concomitant benzodiazepine therapy.

**Maintenance of General Anesthesia**

In adults, an anesthetic can be managed by administering propofol by infusion or intermittent IV bolus injection. The patient’s clinical response will determine the infusion rate and the amount of frequency of incremental injections.

**Continuous Infusion:** Propofol 100 to 250 mcg/kg/min administered in a variable rate infusion with 60%–70% nitrogen oxide and oxygen provides anesthetic support for maintenance of anesthesia. If bolus doses of propofol should immediately follow the induction dose to provide adequate anesthetic support for maintenance of anesthesia. During the induction phase, the initial bolus dose of propofol should be administered within 10 to 15 minutes. Infusion rates should subsequently be decreased 50%–60% during the first half-hour of maintenance.

Other drugs that cause CNS depression (hypotension, hallucinations, nausea, and vomiting) may increase the CNS depression induced by propofol.

**Intermittent Bolus:** Intravenous, increments of propofol 25 mg (2.5 mL) to 50 mg (5 mL) may be administered with nitrous oxide in adult patients undergoing general surgery. The incremental boluses should be administered when changes in vital signs indicate a response to a surgical stimulus or to maintain anesthesia.

Propofol has been used with a variety of agents commonly used in anesthesiology such as amitriptyline, clonazepam, phenytoin, and diazepam, as well as with inhalational and regional anesthetic agents.

In the elderly, debilitated, or ASA III/IV patients, rapid bolus doses should not be used as this will increase cardiovascular effects including hypertension, arrhythmias, airway obstruction, and oxygen desaturation.

**Pediatric Anesthesia**

**Induction of General Anesthesia:** Most pediatric patients 3 years of age or older who can be induced with a halogenated anesthetic or other inhalational agents may be induced with propofol. The infusion rate should be titrated to the patient’s response. In general, the infusion rate should be decreased if the patient exhibits signs of hypotension or tachycardia. In addition, a lower dosage may be recommended for children under 3 years of age.

Atropine 0.01 mg/kg (0.005 mg/kg) should be administered on induction to prevent a bradycardic response to administration of propofol to pediatrics. Rapid boluses for children classified as ASA III or IV, who cannot tolerate an inhalational anesthetic, should be administered only with great caution.

**Propofol administered in a variable rate infusion with nitrous oxide (60%–70%) provides satisfactory anesthesia for most pediatric patients 3 years of age or older, ASA I or II, undergoing general anesthetic procedures.**

**Maintenance of General Anesthesia:** Maintenance by infusion of propofol at a rate of 200-300 mcg/kg/min should immediately follow the induction dose. The following is the handout for propofol. Clinical signs of light anesthesia are present. The infusion should be decreased during this period. Maintenance rates of 125-150 mcg/kg/min are typically needed. However, younger children (5 years of age or less) may require larger maintenance infusion rates than older children.

**Mammography Care Cardiac Care Adult**

When propofol is administered for MAC sedation, rates of administration should be individualized and titrated to clinical response. In most patients, the rate of propofol administration should be not less than 20 mg/min.

**Maintenance of Sedation:** Infusion of propofol should be maintained at a rate sufficient to provide adequate sedation and analgesia for the duration of the procedure. In the event of propofol-induced hypotension, slow titration of the infusion rate should be used to maintain adequate sedation and analgesia.

**ICU Sedation:** (See WARNINGS and DOSAGE AND ADMINISTRATION, Handling Procedures.)

For sedation, mechanically ventilated adult patients, Intensive Care Unit (ICU) sedation should be initiated slowly with a continuous infusion in order to achieve desired clinical effect and minimize hypotension (see DOSAGE AND ADMINISTRATION). Across all US/Canadian clinical studies, the mean induction maintenance rate for all patients was 27.7 ± 22 mg/kg/min. The mean maintenance infusion rates required to maintain adequate sedation ranged from 2.8 mg/kg/min to 13.0 mg/kg/min. The mean rate was increased in patients who are not mechanically ventilated and require additional sedation.

**Adult ICU patients recovering from the effects of general anesthesia or deep sedation will require maintenance rates of 0.5 to 2.5 mg/kg/min to 15.0 to 30.0 mg/kg/min depending on the severity of the effect of general anesthesia or deep sedation.

Although there are reports of induction and analgesic requirements, most patients receive one dose for sedation. However, for some patients, additional doses of propofol may be given during maintenance of sedation. In the event of propofol-induced hypotension or bradycardia, the infusion rate should be decreased to maintain adequate sedation. In the event of propofol-induced hypotension, slow titration of the infusion rate should be used to maintain adequate sedation and analgesia.

In the elderly, debilitated, or ASA III/IV patients, minimal bolus dose administration should be used. For adult patients recovering from the effects of general anesthesia or deep sedation will require maintenance rates of 0.5 to 2.5 mg/kg/min to 15.0 to 30.0 mg/kg/min depending on the severity of the effect of general anesthesia or deep sedation.

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Mucous Membrane Edema

Mucous membrane edema is a common side effect of propofol anesthesia. It typically occurs during intubation and can lead to difficulties with ventilation and airway management. The edema may resolve spontaneously after induction of anesthesia, but in severe cases, it may require intervention such as endotracheal intubation or use of high-flow oxygen therapy. The management of mucous membrane edema should be individualized based on the severity of the edema and the patient's overall condition. 

Conclusion

In conclusion, propofol anesthesia is a widely used technique in modern anesthesia practice. It offers several advantages, including rapid onset and offset, mild side effects, and satisfactory hemodynamic stability. However, its use requires careful monitoring and management to ensure patient safety. Further research is needed to explore the potential long-term effects of propofol anesthesia and to develop strategies to mitigate the risk of complications associated with its use.
**Propofol Injectable Emulsion 1%**

200 mg/20 mL propofol
Contains a Sulfite

**FOR I.V. ADMINISTRATION**
Sterile, nonpyrogenic
Single dose SYRINGE

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**WARNINGS**

- Use strict aseptic technique.
- Contamination can cause fever, infection/sepsis, and/or other life-threatening illness.
- Single patient use.
- Contains no preservative.
- CONTAINS A SULFITE; microbial growth may still be supported.
- Begin use promptly after opening. Discard within specified time limit (See package insert).
- Do not use if contamination is suspected.

**SHAKE WELL BEFORE USE.**

**Usual Dosage:** See Insert.

Each mL contains: 10 mg propofol, 100 mg soybean oil, 22.5 mg glycerol, 12 mg egg yolk phospholipid and 0.25 mg SODIUM METABISULFITE with sodium hydroxide to adjust pH to 4.5-6.6.

Propofol injectable emulsion should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure. Patients should be continuously monitored, and facilities for maintenance of a patent airway, artificial ventilation, and oxygen enrichment and circulatory resuscitation must be immediately available.

Store between 4°-22°C (40°-72°F). Do Not Freeze. Discard unused portion.
NDC 0703-2066-01
Container Label
20 mg/20 mL

(Part No. Y29-286-601)