Propofol Injectable Emulsion, USP

**CONTAINS BENZYL ALCOHOL (see Precautions: Administration of Benzyl Alcohol)**

**PRODUCT INFORMATION**

**WARNINGS**

**What is propofol?**

Propofol is a medication that is administered by injection into a vein or muscle. It is used for various medical purposes, including:

- Sedation during procedures like endoscopy or bronchoscopy
- Anesthesia during surgery
- Sedation during mechanical ventilation

**How should you take propofol?**

Propofol is usually administered by a healthcare professional in a hospital or medical facility. It is not typically given as a take-home medication. The dosage and route of administration will depend on the specific medical condition being treated.

**What should you watch for while taking propofol?**

While taking propofol, you should watch for any adverse reactions or side effects. Contact a healthcare professional if you experience any severe or persistent effects.

**Precautions**

- **Benzyl Alcohol:** Propofol contains benzyl alcohol, which may cause an allergic reaction in some individuals. If you have a history of benzyl alcohol allergy, consult with your healthcare provider before taking propofol.
- **Bacterial Infections:** Infections may develop following the administration of propofol. If you develop a fever, rash, or any signs of infection, contact your healthcare provider.
- **Vascular Occlusions:** Vascular occlusions may occur after propofol injection. If you experience pain or discoloration at the injection site, contact your healthcare provider.
- **Intra-Arterial Injection:** Accidental intra-arterial injection can cause tissue damage. In case of intra-arterial injection, contact your healthcare provider immediately.

**Contraindications**

- **Contraindications to propofol include:**
  - Allergy to propofol or any of its components
  - Hypersensitivity to benzyl alcohol
  - Known allergic reactions to related products

**Warnings**

- **Liver Function:** Propofol may affect liver function. If you have liver disease, consult with your healthcare provider before taking propofol.
- **Pregnancy and Breastfeeding:** Propofol is classified as pregnancy category C. Consult with your healthcare provider before taking propofol if you are pregnant or breastfeeding.
- **Pediatric Use:** Propofol is not recommended for use in children under the age of 2 years.

**Adverse Reactions**

- **Common:** Headache, dizziness, nausea, vomiting, diarrhea, skin reactions, and injection site reactions.
- **Severe:** Allergic reactions, severe cardiovascular reactions, or hypotension.

**Other Information**

- **Key Points:**
  - Propofol is a rapid-acting medication and may cause unconsciousness or loss of consciousness.
  - The duration of action is short, and withdrawal symptoms are rare.

**Drug Interactions**

- **Propofol may interact with:**
  - Other sedatives, anesthetics, or medications that depress the nervous system
  - Alcohol use

**Medication Guide**

Before using propofol, talk to your healthcare provider about what you need to know before using this medication, including if you should take propofol with food, and how propofol may interact with other medications that you take.

**More Information**

For more information, contact your healthcare provider or the manufacturer's information center.

**References**


---

**Table 1: Pharmacology of Propofol**

<table>
<thead>
<tr>
<th>Dosage</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Sedation</td>
</tr>
<tr>
<td>Moderate</td>
<td>Anesthesia</td>
</tr>
<tr>
<td>High</td>
<td>Sedation and Analgesia</td>
</tr>
</tbody>
</table>

**Table 2: Pharmacokinetics of Propofol**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clearance</td>
<td>100 mL/min</td>
</tr>
<tr>
<td>Volume of Distribution</td>
<td>0.5 L/kg</td>
</tr>
<tr>
<td>Half-life</td>
<td>2-3 minutes</td>
</tr>
</tbody>
</table>

**Figure 1: Distribution of Propofol in the Body**

The figure above illustrates the distribution of propofol in the body. The x-axis represents time, and the y-axis represents the concentration of propofol in the bloodstream. The solid line represents the concentration-time curve, and the dashed line represents the elimination of propofol from the body.

**Figure 2: Metabolism of Propofol**

The figure above shows the metabolic pathways of propofol. The different pathways are labeled with their respective enzymes and substrates.

---

**Propofol is a medication that is administered by injection into a vein or muscle. It is used for various medical purposes, including:**

- Sedation during procedures like endoscopy or bronchoscopy
- Anesthesia during surgery
- Sedation during mechanical ventilation

**How should you take propofol?**

Propofol is usually administered by a healthcare professional in a hospital or medical facility. It is not typically given as a take-home medication. The dosage and route of administration will depend on the specific medical condition being treated.

**What should you watch for while taking propofol?**

While taking propofol, you should watch for any adverse reactions or side effects. Contact a healthcare professional if you experience any severe or persistent effects.

**Precautions**

- **Benzyl Alcohol:** Propofol contains benzyl alcohol, which may cause an allergic reaction in some individuals. If you have a history of benzyl alcohol allergy, consult with your healthcare provider before taking propofol.
- **Bacterial Infections:** Infections may develop following the administration of propofol. If you develop a fever, rash, or any signs of infection, contact your healthcare provider.
- **Vascular Occlusions:** Vascular occlusions may occur after propofol injection. If you experience pain or discoloration at the injection site, contact your healthcare provider.
- **Intra-Arterial Injection:** Accidental intra-arterial injection can cause tissue damage. In case of intra-arterial injection, contact your healthcare provider immediately.

**Contraindications**

- **Contraindications to propofol include:**
  - Allergy to propofol or any of its components
  - Hypersensitivity to benzyl alcohol
  - Known allergic reactions to related products

**Warnings**

- **Liver Function:** Propofol may affect liver function. If you have liver disease, consult with your healthcare provider before taking propofol.
- **Pregnancy and Breastfeeding:** Propofol is classified as pregnancy category C. Consult with your healthcare provider before taking propofol if you are pregnant or breastfeeding.
- **Pediatric Use:** Propofol is not recommended for use in children under the age of 2 years.

**Adverse Reactions**

- **Common:** Headache, dizziness, nausea, vomiting, diarrhea, skin reactions, and injection site reactions.
- **Severe:** Allergic reactions, severe cardiovascular reactions, or hypotension.

**Other Information**

- **Key Points:**
  - Propofol is a rapid-acting medication and may cause unconsciousness or loss of consciousness.
  - The duration of action is short, and withdrawal symptoms are rare.

**Drug Interactions**

- **Propofol may interact with:**
  - Other sedatives, anesthetics, or medications that depress the nervous system
  - Alcohol use

**Medication Guide**

Before using propofol, talk to your healthcare provider about what you need to know before using this medication, including if you should take propofol with food, and how propofol may interact with other medications that you take.

**References**

Incidence greater than 1% - Probably Causally Related

represent estimates of the percentage of clinical trial patients which appeared to have a probable causal relationship.

trials, apnea is frequently observed in pediatric patients.

Anesthesia in Pediatric Patients

Events without an * or % had an incidence of 1% to 3%.

OVERDOSAGE

Shake well before use. Do not use if there is evidence of excessive creaming or aggregation, if large droplets are visible, or if

Propofol blood concentrations at steady-state are generally proportional to infusion rates, especially in individual patients.

Special Senses: Diplopia, Ear Pain, Eye Pain, Nystagmus, Taste

Hematologic/Lymphatic: Coagulation Disorder, Leukocytosis

Cardiovascular: Arrhythmia, Atrial Fibrillation, Atrioventricular

Body as a Whole:

Cardiovascular Bradycardia Bradycardia

Hiccough, Hyperventilation, Hypoventilation, Hypoxia,

Nausea, Swallowing, Vomiting

Cramping, Diarrhea, Dry Mouth, Enlarged Parotid,

Opisthotonos, Rigidity, Seizures, Somnolence, Tremor,

Confusion, Delirium, Depression, Dizziness, Emotional

Cloudy Urine

Agitation

Hypertension, Seizures, Somnolence,

Bigeminy, Cardiac Arrest,

Fever, Sepsis, Trunk Pain, Whole

SUMMARY OF DOSAGE GUIDELINES

DOSAGE AND ADMINISTRATION

Maintenance of MAC Sedation

For maintenance of MAC sedation, a method is preferable over an intermittent bolus technique. With the

Maintenance

Maintenance of

DOSAGE AND ADMINISTRATION

Guidelines for Aseptic Technique for General Anesthesia/MAC Sedation

Strict aseptic technique must always be maintained during handling. Propofol injectable emulsion is a single access parenteral

Three cases of self-administration of propofol by health care professionals have been reported, including a registered nurse who injected herself to reduce the pain associated with an intravenous line and a registered nurse who injected herself to reduce postoperative pain. The nurses showed evidence of propofol intoxication, including behavioral and physical symptoms of sedation.

In adults, anesthesia can be maintained by administering propofol injectable emulsion by infusion or intermittent IV bolus

Maintenance of

For intubated, mechanically ventilated adult patients, Intensive Care Unit (ICU) sedation should be initiated slowly

In adults, anesthesia can be maintained by administering propofol injectable emulsion by infusion or intermittent IV bolus

Maintenance

For maintenance of sedation, a variable rate infusion method is preferable over an intermittent bolus dose method. With the

Maintenance

For intubated, mechanically ventilated adult patients, Intensive Care Unit (ICU) sedation should be initiated slowly

DOSAGE AND ADMINISTRATION

Guidelines for Aseptic Technique for General Anesthesia/MAC Sedation

Strict aseptic technique must always be maintained during handling. Propofol injectable emulsion is a single access parenteral

Three cases of self-administration of propofol by health care professionals have been reported, including a registered nurse who injected herself to reduce the pain associated with an intravenous line and a registered nurse who injected herself to reduce postoperative pain. The nurses showed evidence of propofol intoxication, including behavioral and physical symptoms of sedation.

In adults, anesthesia can be maintained by administering propofol injectable emulsion by infusion or intermittent IV bolus

Maintenance of

For maintenance of sedation, a variable rate infusion method is preferable over an intermittent bolus dose method. With the

Maintenance

For maintenance of sedation, a variable rate infusion method is preferable over an intermittent bolus dose method. With the

Maintenance

For maintenance of sedation, a variable rate infusion method is preferable over an intermittent bolus dose method. With the

Maintenance

For maintenance of sedation, a variable rate infusion method is preferable over an intermittent bolus dose method. With the

Maintenance

For maintenance of sedation, a variable rate infusion method is preferable over an intermittent bolus dose method. With the

Maintenance

For maintenance of sedation, a variable rate infusion method is preferable over an intermittent bolus dose method. With the

Maintenance