

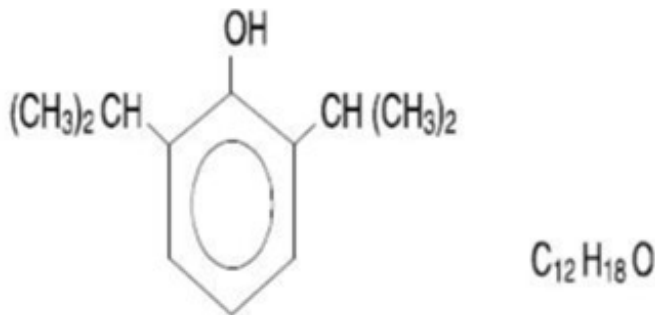
## **PROPOFOL 1%- propofol 1% injection, emulsion**

### **Genixus**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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Propofol injectable emulsion, USP is a sterile, nonpyrogenic white or almost white, homogeneous emulsion, containing 10 mg/mL of propofol, USP suitable for intravenous administration. Propofol, USP is chemically described as 2,6-diisopropylphenol and has a molecular weight of 178.27.

The structural formula is:



Propofol, USP is slightly soluble in water and, thus, is formulated in a white, oil-in-water emulsion.

The pKa is 11. The octanol/water partition coefficient for propofol, USP is 6761:1 at a pH of 4.5 to

7.4. In addition to the active component, propofol, USP the formulation also contains soybean oil (100 mg/mL), glycerol (22.5 mg/mL), egg phospholipids (12 mg/mL); and benzyl alcohol

(0.15%); with sodium hydroxide to adjust pH. Propofol injectable emulsion, USP is isotonic and has a pH of 5.5 to 7.4.

1 2 3 4 5 6 7 8 9 10  
L-11310-AC  
Approx. ml

# PROPOFOL 1%

Injectable Emulsion, USP. Sterile, nonpyrogenic. Not for Resale. Office use only. Rx only. Single Patient Use Only. For Intravenous Administration. **Dosage:** See package insert.

**100mg/10ml**  
(10mg/1ml) Store between 4° to 25°C (40° to 77°F). Do not freeze.

**SHAKE WELL BEFORE USING**  
Use strict aseptic technique  
Contains Benzyl Alcohol, which inhibits microbial growth up to 12 hours, discard within 12 hours of opening.

This drug product was repackaged by GENIXUS  
Kannapolis, NC 28081 1-833-436-4987  
To report SUSPECTED ADVERSE REACTIONS contact FDA  
at [www.FDA.gov/medwatch](http://www.FDA.gov/medwatch) or 1-800-FDA-1088

NDC 80700 113 10



2 4 6 8 10 12 14 16 18 20  
L-11320-AB  
Approx. ml

# PROPOFOL 1%

Injectable Emulsion, USP. Sterile, nonpyrogenic. Not for Resale. Office use only. Rx Only. Single Patient Use Only. For Intravenous Administration. **Dosage:** See package insert.

**200mg/20ml**  
(10mg/1ml) Store between 4° to 25°C (40° to 77°F). Do not freeze.

**SHAKE WELL BEFORE USING**  
Use strict aseptic technique  
Contains Benzyl Alcohol, which inhibits microbial growth up to 12 hours, discard within 12 hours of opening.

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NDC 80700 113 20



## PROPOFOL 1%

propofol 1% injection, emulsion

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:80700-113(NDC:43598-549)
<b>Route of Administration</b>	INTRAVENOUS		

### Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
PROPOFOL (UNII: YI7VU623SF) (PROPOFOL - UNII:YI7VU623SF)		PROPOFOL	10 mg in 1 mL	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
GLYCERIN (UNII: PDC6A3C0OX)		22.5 mg in 1 mL		
SOYBEAN OIL (UNII: 241ATL177A)		100 mg in 1 mL		
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)		12 mg in 1 mL		
BENZYL ALCOHOL (UNII: LKG8494WBH)		0.0015 mg in 1 mL		
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80700-113-11	10 in 1 BAG	03/29/2023	
1	NDC:80700-113-10	10 mL in 1 SYRINGE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:80700-113-12	25 in 1 BAG	03/29/2023	
2	NDC:80700-113-10	10 mL in 1 SYRINGE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
3	NDC:80700-113-21	10 in 1 BAG	03/29/2023	
3	NDC:80700-113-20	20 mL in 1 SYRINGE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
4	NDC:80700-113-22	25 in 1 BAG	03/29/2023	
4	NDC:80700-113-20	20 mL in 1 SYRINGE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		03/29/2023		

**Labeler** - Genixus (117436254)

### Establishment

Name	Address	ID/FEI	Business Operations
Genixus		117436254	repack(80700-113) , analysis(80700-113)

Revised: 12/2023

Genixus