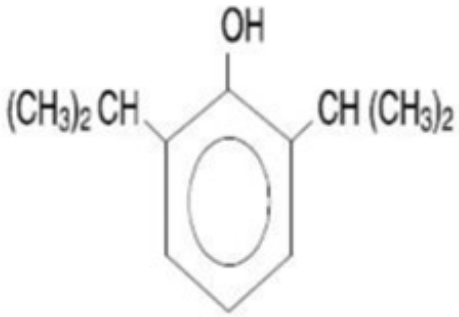
PROPOFOL 1%- propofol 1% injection, emulsion
Genixus

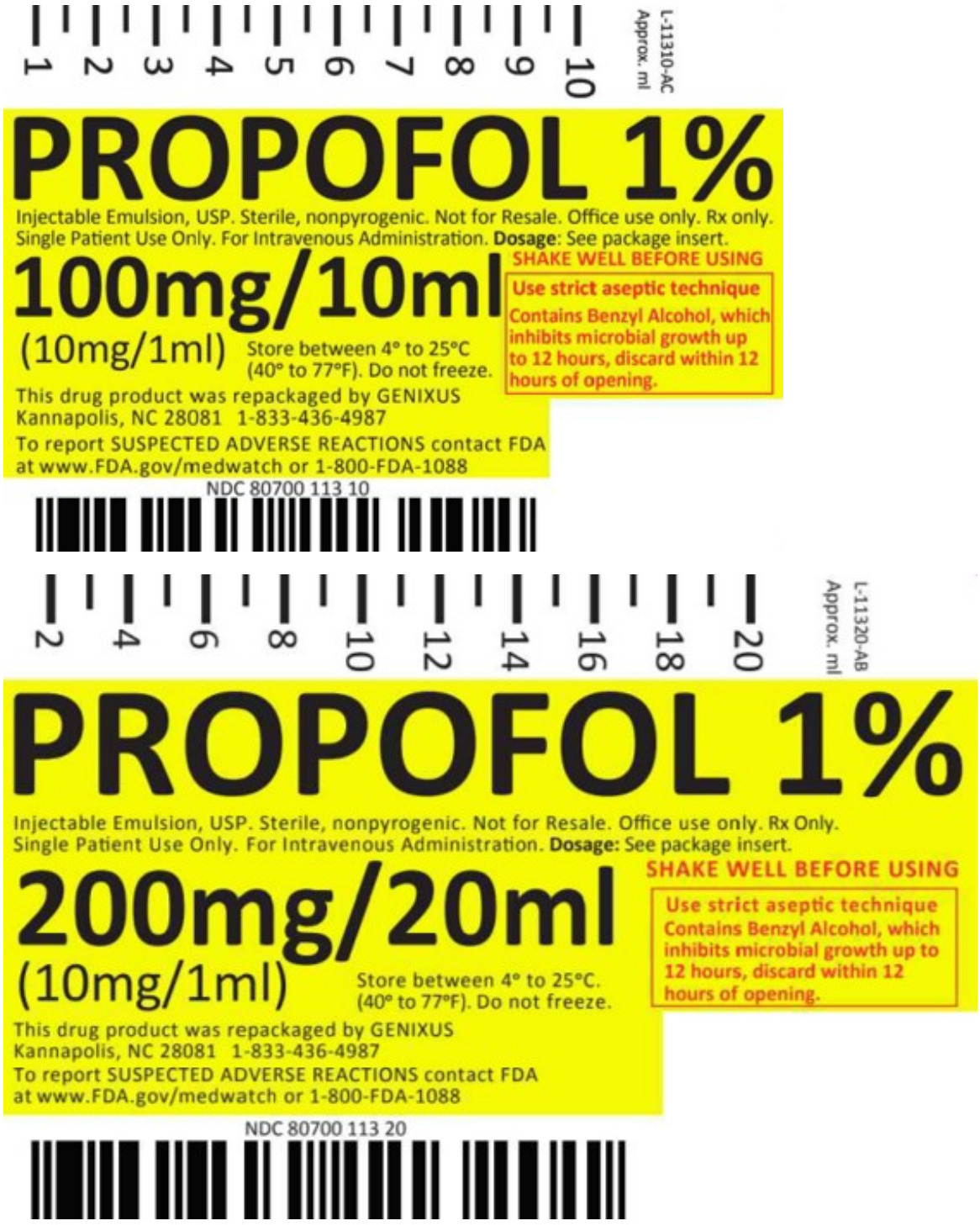
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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:



$C_{12}H_{18}O$

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.



PROPOFOL 1%

propofol 1% injection, emulsion

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:80700-113(NDC:43598-549)
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PROPOFOL (UNII: YI7VU623SF) (PROPOFOL - UNII:YI7VU623SF)	PROPOFOL	10 mg in 1 mL

Inactive Ingredients

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

Packaging

#	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.)		

Marketing Information

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