Special Propofol Alert

Key Differences between Fresenius Propoven 2% (Propofol 20 mg per mL) Emulsion for Injection or Infusion and Diprivan® Injectable Emulsion, USP 10 mg per mL

Important Information	Fresenius Propoven 2% (propofol 20 mg per mL) Emulsion	Diprivan Injectable Emulsion, USP 10 mg per mL
Fresenius Propoven 2% (propofol 20 mg per mL) is **double the concentration** of US approved Diprivan® 10 mg per mL (propofol 1%). Exercise caution and implement steps to ensure dosing calculations, infusion rates, and infusion pump settings are accurate.		
Active Ingredient	Propofol	Propofol
Concentration	**20 mg per mL (2%)**	10 mg per mL (1%)
Strength	2,000 mg per 100 mL	1,000 mg per 100 mL
Fill Volume	100 mL	100 mL
Description	Single Dose Vial for Single Patient Use Only	Single Dose Vial for Single Patient Use Only
Anti-microbial Retardant	Does not contain ethylenediaminetetraacetic acid (EDTA)	Contains EDTA
Excipients	Contains a combination of medium-chain triglycerides (MCT) and long-chain triglycerides (LCT)	Contains long-chain triglycerides (LCT)

Fresenius Propoven 2% Emulsion contains the same active ingredient, propofol, as DIPRIVAN®, but in a higher concentration. **Propoven 2% has double the concentration of propofol compared to DIPRIVAN®. Special attention is needed to ensure accurate dosing calculations and infusion rates.**

- Consider addition of the new concentration (20 mg per mL) to the drug library of the respective pumps and to electronic health records (EHR).
- Institutions should confirm that barcode systems provide correct information when the product is scanned. The barcode used on Fresenius Propoven 2% Emulsion is an international pharmaceutical manufacturing code and may not be appropriately recognized by scanning systems used in the United States.

Institutions should take extra care during preparations and administration as the Fresenius Propoven 2% (propofol 20 mg per mL) labeling information is NOT expressed in typical US format (total strength per total volume).

For questions regarding Fresenius Propoven 2% Emulsion in the United States, please contact
Fresenius Kabi USA Medical Affairs at 1-800-551-7176 Option 3,
Monday – Friday, between the hours of 8 a.m. and 5 p.m. (CST)
or e-mail: medinfo.USA@fresenius-kabi.com

SEE AUTHORIZED FACT SHEET FOR HEATHCARE PROVIDERS

- Fresenius Propoven 2% Emulsion is not FDA-approved
- Fresenius Propoven 2% Emulsion has been authorized by FDA for use under an Emergency Use Authorization (EUA)
- Fresenius Propoven 2% Emulsion is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner

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