

**FDA ADVISORY**

No. **2024-0637**

8 APR 2024

**TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

**SUBJECT : Public Health Warning Against the Purchase and Use of the Following Unregistered Drug Products:**

1. **Ropivacaine HCl Injection, USP 0.5% 150 mg/ 30 mL (5 mg/mL) 30 mL Single-Dose Vial**
2. **Diprivan® (Propofol) Injectable Emulsion, USP 200 mg per 20 mL (10 mg per mL) 20 mL Vial**


The Food and Drug Administration (FDA) advises the public against the purchase and use of the following unregistered drug products:

Rx only
NDC 70069-064-10  
10 x 30 mL Single-Dose Vials

## Ropivacaine HCl Injection, USP

**0.5%**  
**150 mg/30 mL**  
(5 mg/mL)

For Infiltration, Nerve Block, and Epidural Administration Only.  
Not for Intravenous Administration.




**Each mL contains:**  
Ropivacaine HCl 5 mg, Sodium chloride 8 mg, Sodium hydroxide and/or hydrochloric acid to adjust pH to 4.0 to 6.0.

**Contains no preservatives.**  
Discard unused portion. Single dose container.

Consult package insert for dosage and full prescribing information.  
Solution may be autoclaved (see package insert for instructions).  
Do not use if solution is discolored or contains a precipitate.

**Storage:** Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

This container closure is not made with natural rubber latex.



**Ropivacaine HCl Injection, USP 0.5% 150 mg/ 30 mL (5 mg/mL) 30 mL Single-Dose Vial**  
by Somerset Therapeutics, LLC - Hollywood, FL 33024

Figure 1. Unregistered drug product





NDC 63323-269-29      260929

**DIPRIVAN<sup>®</sup>**  
*(Propofol)* INJECTABLE  
 EMULSION, USP

**200 mg per 20 mL**  
 (10 mg per mL)

**FOR INTRAVENOUS ADMINISTRATION**  
**SHAKE WELL BEFORE USING**

Ten 20 mL vials  
 For Single Patient Use Only

*Sterile, nonpyrogenic*

**Dosage:** See package insert.

In addition to the active component, propofol, the formulation contains: soybean oil (100 mg/mL), glycerol (22.5 mg/mL), egg lecithin (12 mg/mL) and disodium edetate (0.005%); with sodium hydroxide to adjust pH.

DIPRIVAN Injection 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° to 25°C (40° to 77°F). Do not freeze.

- Use strict aseptic technique
- Contains EDTA, which inhibits microbial growth up to 12 hours, discard within 12 hours of opening

Rx only

DIPRIVAN is a trademark of Fresenius Kabi USA, LLC.

Manufactured for:  
**FRESENIUS KABI**  
 Fresenius Kabi  
 Lake Zurich, IL 60047  
 Made in Sweden

337 118      260929



**Diprivan<sup>®</sup> (Propofol) Injectable Emulsion, USP 200 mg per 20 mL (10 mg per mL)**  
**20 mL Vial**  
 Traded by: Fresenius Kabi - Lake Zurich, IL

Figure 2. Unregistered drug product

FDA Post-Marketing Surveillance (PMS) activities have verified that the abovementioned drug products have not gone through the registration process of the Agency and have not been issued with proper authorization in the form of Certificate of Product Registration. Thus, the Agency cannot guarantee their quality, safety and efficacy. Therefore, consumption of such violative products may pose potential danger or injury to health.

Pursuant to Republic Act No. 9711, otherwise known as the “Food and Drug Administration Act of 2009”, the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, promotion, advertising or sponsorship of health products without proper authorization from FDA is prohibited.

All concerned establishments and/or entities are warned not to distribute the above-identified violative drug products until they have already been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if the products are registered with the FDA by using the **FDA Verification Portal** feature accessible at <https://verification.fda.gov.ph>.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that these products are not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at [info@fda.gov.ph](mailto:info@fda.gov.ph). To report continuous sale or distribution of unregistered health products, kindly e-mail us via [ereport@fda.gov.ph](mailto:ereport@fda.gov.ph). You may also call the Center for Drug Regulation and Research at telephone number (02) 8809-5596. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: <https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH> and fill out all the required fields.

Dissemination of the information to all concerned is requested.

  
DR. SAMUEL A. ZACATE  
Director General

DTN:   
20240216153204