



FDA ADVISORY
No: 20230946

09 MAY 2023

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Product Recall of Specific Lot of Isopropyl Alcohol 70%

All healthcare professionals and the general public are hereby warned by the Food and Drug Administration (FDA) that the affected lot of the subject product is being recalled from the market. The details of the product are as follows:

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|------------------|---|
| DRUG PRODUCT | Isopropyl Alcohol 70% Solution [Sampaguita] |
| REGISTRATION NO. | DRHR-264 |
| LOT NO. | E220118 |
| MANUFACTURER | Lejal Laboratories, Inc.- Km. 18 McArthur Highway, Meycauayan, Bulacan, Philippines |
| TRADER | Galenica Pharmaceuticals, Inc. located at No. 15 Lejal St., Banga, Meycauayan, Bulacan |



Figure 1. Isopropyl Alcohol 70% Solution [Sampaguita] for Recall



Isopropyl Alcohol (70% concentration) is used as a topical antiseptic and disinfectant. Based on the results of the laboratory analyses conducted by the FDA, it was found that the specific lot contains amount of **Methanol**.



Methanol is a toxic alcohol that is used industrially as a solvent, pesticide, and alternative fuel source which can be absorbed into the body by inhalation, ingestion, skin contact, or eye contact. Effects of short-term exposure (less than 8-hours) may cause an accumulation of acid in the blood (metabolic acidosis), blindness, and death. Initial adverse health effects due to methanol poisoning include drowsiness, reduced level of consciousness (CNS depression), confusion, headache, dizziness, inability to coordinate muscle movement (ataxia), and heart and respiratory (cardiopulmonary) failure. Chronic poisoning from repeated exposure may produce inflammation of the eye (conjunctivitis), insomnia, stomach disturbances, visual failure, and irritation of the skin (dermatitis)^[1].

Therefore, distributors, hospitals, retailers, pharmacies, or clinics that have the affected lot of the product are instructed to discontinue further distribution, sale, and use. Likewise, all consumers are advised not to use or purchase the affected product lot and may contact Galenica Pharmaceuticals, Inc. through galenicapharminc@yahoo.com for any question or additional information regarding the recall.

All Local Government Units (LGU) and Law Enforcement Agencies (LEAs) are requested to ensure that the affected product lot is not sold or made available in their localities or areas of jurisdiction.

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

Dissemination of the information to all concerned is requested.


DR. SAMUEL A. ZACATE
Director General 



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^[1] "METHANOL: Systemic Agent", 2011, https://www.cdc.gov/niosh/ershdb/emergencyresponsecard_29750029.html (accessed April 2023)