



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



FDA ADVISORY  
No. **2021-1934**

02 AUG 2021

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

**SUBJECT : Public Health Warning Against the Purchase and Use of the Unregistered Drug Product "Maden™ Povidone –Iodine (Thetadine) 60 mL"**

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



**Maden™ Povidone –Iodine (Thetadine) 60 mL**

Manufactured by: Arcemar Laboratories – Ruiz Village, San Antonio, Agdao  
Davao City, Philippines

Figure 1. Unregistered drug product



FDA Post-Marketing Surveillance (PMS) activities have verified that the above mentioned drug product has not gone through the registration process of the Agency and has not been issued with proper authorization in the form of Certificate of Product Registration. Thus, the Agency cannot guarantee its quality, safety and efficacy. Therefore, consumption of such violative product 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 product without proper authorization from FDA is prohibited.

All concerned establishments and/or entities are warned not to distribute the above-identified violative drug product until it has been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that this product is 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.

  
**ROLANDO ENRIQUE D. DOMINGO, MD**  
Director General

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