



24 JAN 2022

FDA ADVISORY
No. **2022-0042**

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT : Public Health Warning Against the Purchase and Use of the Unregistered Drug Product "We Care" Antiseptic Povidone-Iodine Prep Pad 100's

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

Antiseptic
Povidone-Iodine Prep Pad

"We Care"

Cautions:

1. Single use only, discard after use
2. External use only, avoid contact with eyes
3. Keep out of reach of children

Saturated with 10% Povidone-Iodine Solution. **100PCS**

Antiseptic
Povidone-Iodine
Prep Pad
1 Premoistened Towelette
Package Not Child-Resistant

Drug Facts

Active Ingredients	Purpose
10% Povidone-Iodine Solution	Antiseptic

Drug Facts (continued)

Uses
Wipe over the required area

Warnings
For external use only. Flammable, keep away from fire or flame.
Do not use: in large quantities, over large areas of the body; in eyes; over raw or blistered areas.
Stop use and ask a doctor if conditions worsen or persist for more than 7 day or clear up and occur again within a few days.

Keep out of reach of children.
If swallowed get medical help or contact Poison Control Center right away.

Directions Adults and Children 2 year and older: Apply to cleaned affected area not more than 3 times daily. Children under 2 years of age: Consult a doctor.

Inactive Ingredients 10% Povidone-Iodine Solution

"We Care" Antiseptic Povidone-Iodine Prep Pad 100's

Figure 1: Unregistered drug product



FDA Post-Marketing Surveillance (PMS) activities have verified that the abovementioned 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 and safety. 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 products 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. Always check if a product is 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 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. To report continuous sale or distribution of unregistered health products, 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. 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.


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