



FDA ADVISORY
No. **2022-1531**

01 SEP 2022

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT : Public Health Warning Against the Purchase and Use of the Unregistered Drug Product "Natural Green Leaf Hemorrhoids Cream 20g"

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

Natural Green Leaf HEMORRHOIDS CREAM
Fast soothing relief from hemorrhoid pain, itching, burning and discomfort.
20g

DICTAMNI Natural ANTIBACTERIAL OTC

Indications: Fast soothing relief from hemorrhoid pain, itching, burning and discomfort. Relieves internal and external hemorrhoid symptoms. Shrinks swollen hemorrhoidal tissue. Helps relieve pain on contact by providing a soothing layer of protection. Protects against further irritation.
Main ingredients: Cortex dictamni, sophora, camphor, lanolin, petrolatum, cnidium, pseudolaric chlorhexidine acetate (0.40%-0.45%). This product is against candida albicans and staphylococcus aureus, escherichia coli has an inhibitory effect.
Directions: Apply over the affected area. Gently massage onto skin 2-3 times daily.
Precautions: For external use only. Discontinue use if irritation occurs or if you have allergies. Do not use on children under two years old. This product should not be used by pregnant women. Keep out of children's reach.
Shelf life: 3 years. Store in a cool dry place away from sunlight.

Imported by: Cha-Ken Consumer Goods Trading.
Address: 602A, 611 Tytana Bldg., Tytana St., Plaza Lorenzo Ruiz, Binondo, Manila.

Made in P.R.C.

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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.


DR. SAMUEL A. ZACATE
Director General

DTN: 

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