



23 JUN 2021

FDA ADVISORY
No. **2021-1492**

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT : Public Health Warning Against the Purchase and Use of the Unregistered Drug Product "Desitin® Rapid Relief Zinc Oxide Diaper Rash Cream"

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

Desitin® Rapid Relief Zinc Oxide Diaper Rash Cream

Wholesaler: Johnson & Johnson Consumer Products Company - Division of Johnson & Johnson Consumer Companies, Inc. Skillman, NJ 08558-9418

Drug Facts		Drug Facts (continued)		Drug Facts (continued)	
Active ingredient Zinc oxide 13% <i>See packaging for more information.</i>	Purpose Skin protectant	Stop use and ask a doctor if • condition worsens • symptoms last more than 7 days or clear up and occur again within a few days	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	Other information • store at 20° to 25° C (68° to 77° F) • may stain clothing	Inactive ingredients Water, Mineral Oil, Petrolatum, Beeswax, Dimethicone, Sorbitan Sesquisebacate, Microcrystalline Wax, PEG-20 Dipolyhydroxyoleate, Magnesium Sulfate, Thymocyanolol, Methylparaben, Potassium Hydroxide, Propylparaben, Tocopheryl Acetate, Aloe Barbadensis Leaf Juice
Uses • helps treat and prevent diaper rash • protects chafed skin due to diaper use and helps soothe out wetness.	Warnings For external use only. When using this product: • do not get into eyes.	Directions • change wet and soiled diapers promptly • cleanse the diaper area • allow to dry • apply cream liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged.	Questions? Call toll-free 800-726-3643 or 215-273-8795 (protect).		

Desitin® Rapid Relief Cream instantly forms a protective layer on your baby's skin to soothe and relieve rash discomfort, providing relief from first use. This fragrance-free, hypoallergenic, dermatologist-tested creamy formula goes on smoothly and wipes off easily, making **DESITIN® Rapid Relief Cream** your every day partner in protecting against and treating diaper rash for relief your baby can feel.

Active Trade in Elements
Distributed in the U.S. by
JOHNSON & JOHNSON CONSUMER PRODUCTS COMPANY
Division of Johnson & Johnson Consumer Companies, Inc.
Skillman, NJ 08558-9418 © J&J CCI 2012 30022499

For information on preventing and treating diaper rash, visit www.desitin.com

NET WT 4 Oz (113 g)

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 their 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.

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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Director General

DTN:



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