



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



23 JUN 2021

**FDA ADVISORY**  
No. 2021-1492-A

**PARA : SA LAHAT NG HEALTHCARE PROFESSIONALS AT SA PUBLIKO**

**PAKSA : Babala sa Publiko Tungkol sa Pagbili at Paggamit ng Hindi Rehistradong Gamot na "Desitin® Rapid Relief Zinc Oxide Diaper Rash Cream"**

Pinapayuhan ng Food and Drug Administration (FDA) ang publiko laban sa pagbili at paggamit ng hindi rehistradong gamot na:

**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

<p><b>Drug Facts</b></p> <p><b>Active ingredient</b> Purpose Zinc oxide 17% Skin protectant</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>Helps treat and prevent diaper rash</li> <li>Protects chapped skin due to diaper rash and helps seal out irritants</li> </ul> <p><b>Warnings</b> For external use only When using this product: • do not get into eyes</p>	<p><b>Drug Facts (continued)</b></p> <p>Stop use and ask a doctor if:</p> <ul style="list-style-type: none"> <li>condition worsens</li> <li>symptoms last more than 7 days or clear up and occur again within a few days</li> </ul> <p>Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>change wet and soiled diapers promptly</li> <li>cleanse the diaper area</li> <li>apply to dry</li> <li>apply often liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged</li> </ul>	<p><b>Drug Facts (continued)</b></p> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>store at 20° to 25°C (68° to 77°F)</li> <li>may stain clothing</li> </ul> <p><b>Inactive ingredients</b> Water, Mineral Oil, Petroleum, Beeswax, Dimethicone, Sorbitan Sesquisebacate, Microcrystalline Wax, PEG-30 Dipolyhydroxystearate, Magnesium Sulfate, Phenoxyethanol, Methylparaben, Potassium Hydroxide, Propylparaben, Tocopheryl Acetate, Aloe Barbadensis Leaf Juice</p> <p><b>Questions?</b> Call toll-free 800-729-3843 or 215-273-8756 (ask for)</p>
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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 Made in Cosmos  
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.jnj.com](http://www.jnj.com)

SUSTAINABLE CUSTODY PARTNER  
Certified Chain of Custody  
All our 100% Certified Forest Content  
[www.fsc.org](http://www.fsc.org)  
for more

0 74300 00301 6

Larawan 1. Hindi rehistradong gamot

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Trunk Line +63 2 857 1900 Fax +63 2 807 0751  
Website: [www.fda.gov.ph](http://www.fda.gov.ph) Email: [info@fda.gov.ph](mailto:info@fda.gov.ph)



Management System  
ISO 9001:2015  
[www.tuv.com](http://www.tuv.com)  
ID: 9105073396



Napatunayan sa pamamagitan ng isinagawang *Post-Marketing Surveillance* (PMS) ng FDA na ang nasabing gamot ay hindi dumaan sa proseso ng rehistrasyon ng Ahensya at hindi nabigyan ng kaukulang awtorisasyon tulad ng *Certificate of Product Registration* (CPR). Dahil dito, hindi masisiguro ng Ahensya ang kalidad, kaligtasan at bisa nito. Samakatuwid, ang paggamit ng nasabing iligal na produkto ay maaaring magdulot ng panganib sa kalusugan.

Alinsunod sa *Republic Act No. 9711*, o ang *Food and Drug Administration Act of 2009*, ang paggawa, pag-angkat, pagbenta, pamamahagi, paglipat, promosyon, pagpapatalastas o *sponsorship* ng produktong pangkalusugan nang walang kaukulang awtorisasyon mula sa FDA ay ipinagbabawal.

Ang lahat ng establisyamento at/o entidad ay binabalaang huwag mamahagi ng nasabing iligal na produkto hanggang sa ito ay mabigyan ng kaukulang awtorisasyon. Karampatang parusa ay mahigpit na ipatutupad sa mga lalabag.

Hinihiling sa lahat ng *Local Government Units* (LGUs) at *Law Enforcement Agencies* (LEAs) na tiyaking ang produktong ito ay hindi maibebenta o magagamit sa kanilang mga nasasakupan.

Para sa karagdagang impormasyon at katanungan, maaaring mag-email sa [info@fda.gov.ph](mailto:info@fda.gov.ph). Upang mag-report ng patuloy na pagtitinda o pangangalakal ng mga hindi rehistradong gamot, mag-email sa [ereport@fda.gov.ph](mailto:ereport@fda.gov.ph). Maaari ring tumawag sa *Center for Drug Regulation and Research* (CDRR) sa numerong (02) 8809-5596. Para sa mga hinihinalang hindi kanais-nais na reaksyon sa gamot, i-report agad sa FDA gamit ang link na ito: <https://primary-reporting.who-umc.org/Reporting/Reporter?OrganizationID=PH> at kumpletuhin ang mga kinakailangang impormasyon.

Ang lahat ay hinihikayat na palaganapin ang mga nakasaad na impormasyon.

  
ROLANDO ENRIQUE D. DOMINGO, MD  
Director General

DTN: 

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