



03 DEC 2021

FDA ADVISORY  
No. **2021-3307**

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

**SUBJECT : Public Health Warning Against the Purchase and Use of the Following Unregistered Drug Products:**

1. DHC C 1000 mg [Label in Foreign Language]
2. Estradiol Valerate Injection USP Progynon® Depot 10 mg/mL 10 amps 1 mL
3. Prosexol Tablets TZ316 0.5 mg Tablets

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



**DHC C 1000 mg [Label in Foreign Language]**

Figure 1. Unregistered drug



**Progynon® Depot**  
प्रोजिनन डेपो

Batch No. AKK1045  
Mfg. Date 05/2019  
Exp. Date 05/2023

Maximum Retail Price Rs. 37.30 per ampoule (Inclusive of All Taxes)

10 mg/ml

10 amps, 1 ml

intra-muscular

Rx  
**Estradiol Valerate Injection USP**  
**Progynon® Depot** 10 mg/ml प्रोजिनन डेपो

Each ml contains: Estradiol Valerate USP 10 mg, Arachis Oil IP q.s.

Mfg. Lic. No. KD/2666-A  
Marketed by: German Remedies (A Division of Cadila Healthcare Limited)  
Manufactured by: Cadila Healthcare Ltd. C/O J.K. Enterprise, 4, Luthra Indl. Premises, Andheri-Kurla Road, Mumbai 400 072, Maharashtra  
Mfg. At: C-30/12, TTC Industrial Area, MIDC, Powane Village, Navi Mumbai 400708  
Regd. Trademark


Store, protected from light

SCHEDULE H DRUG  
WARNING: To be sold by retail on the prescription of a Registered Medical Practitioner only.

10 mg/ml

10 amps, 1 ml


intra-muscular



**Estradiol Valerate Injection USP Progynon® Depot 10 mg/mL 10 amps 1 mL**  
Marketed by: German Remedies  
Manufactured by: Cadila Healthcare Ltd. - C/O J.K. Enterprise, 4, Luthra Indl., Premises, Andheri-Kurla Road, Mumbai 400 072 Maharashtra

Figure 2. Unregistered drug





**Prosexol Tablets TZ316 0.5 mg Tablets**

Figure 3. Unregistered drug

FDA Post-Marketing Surveillance (PMS) activities have verified that the abovementioned drug products have not gone through the registration process of the Agency and have not been issued with proper authorization in the form of Certificate of Product Registration. Thus, the Agency cannot guarantee their quality, safety and efficacy. Therefore, consumption of such violative products may pose potential danger or injury to health.

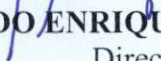
Pursuant to Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, promotion, advertising or sponsorship of health products without proper authorization from FDA is prohibited.

All concerned establishments and/or entities are warned not to distribute the above-identified violative drug products until they have already been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if the products are registered with the FDA by using the **FDA Verification Portal** feature accessible at <http://verification.fda.gov.ph>.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that these products are 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

DTN:   
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