



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. 2024-0500-A

07 MAR 2024

TO : SA LAHAT NG HEALTHCARE PROFESSIONALS AT SA PUBLIKO

SUBJECT : Babala sa Publiko tungkol sa Paggamit ng Beripikadong Pekeng Gamot na “Valium® (Diazepam) 10 mg/2 mL Solution for Injection I.M./I.V. 5 ampoules of 2 mL”

Pinapayuhan ng Food and Drug Administration (FDA) ang publiko laban sa pagbili at paggamit ng beripikadong pekeng gamot:



TUNAY/ AUTHENTIC

10 ampoules of 2 mL

Diazepam Valium®

5 mg/mL (10mg/2mL)

Solution for injection (i.m./i.v.)
Anxiolytic


Rx

Made for Atriahs Pharma UK Limited, United Kingdom
by Cenexi SAS, Fontenay-sous-Bois, France


Imported by
DKSH Market Expansion Services Philippines, Inc.
8th Floor, Cyber Sigma, Lawton Avenue
Mckinley West, Fort Bonifacio
Taguig City

For i.m., if necessary i.v. injection
Anxiolytic
Medicine: keep out of reach of children
Dosage and administration: see package insert
Store at temperatures not exceeding 30°C
Keep container in outer carton
Caution: Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.
Dangerous drug - To be prescribed by a PDEA S-2 Licensed Practitioner in Triplicate Prescription form.
It is a habit forming drug

FORMULATION:
Each ml contains: 5 mg Diazepam
For suspected adverse drug reaction, please report to the Food and Drug Administration (FDA) at www.fda.gov.ph and to the DKSH Philippines, Inc. Local Safety Unit via email at pharmacovigilance.ph@dksh.com.
At the first sign of any adverse drug reaction, the patient should seek medical attention immediately



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PEKE/ COUNTERFEIT

Valium® (Diazepam) 10mg

5 ampoules of 2 ml



B. NO. 101067 ID 099
MFD. 10-2022 EXP. 10-2026

Each ampoule contains:
2ml=10mg diazepam (U.S.P.)
Mfg. Lic. No. 000267
Regn. No. 000584

Made under licence from
F. Hoffmann-La Roche Ltd.
Basel, Switzerland,
By CENEXI SAS,
Fontenay-Sous-Bios, France



Peke/Counterfeit – Ang mga batch numbers at product labeling hindi tugma sa rehistradong gamot.

Made under license from F. Hoffmann-La Roche Ltd., Basel, Switzerland
by CENEXI SAS, Fontenay-Sous-Bios, France

Larawan 1. Paghahambing sa Tunay/Authentic at Peke/Counterfeit na Valium® (Diazepam) 10 mg/2 mL Solution for Injection I.M./I.V. 5 ampoules of 2 mL (Batch Nos. 101067 and 99375)

Ang lahat ng *healthcare professionals* at publiko ay binabalaan tungkol sa paglipana ng nasabing pekeng gamot sa merkado na maaaring magdulot ng panganib sa kalusugan ng mga gagamit nito. Ang publiko ay pinapaalalahanan ring bumili lamang sa mga establisyementong lisensyado ng FDA.

Gayundin, ang lahat ng establisyemento ay binabalaang huwag magbenta ng pekeng gamot na nagtataglay ng mga nasabing katangian. Ang pagaangkat, pagbebenta at pamamahagi nito ay paglabag sa *Republic Act No. 9711 or the Food and Drug Administration Act of 2009*, and *Republic Act No. 8203 or the Special Law on Counterfeit Drugs*. Ang sino mang mapatunayang nagbebenta ng nasabing pekeng produkto ay mapaparusahan.

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

Para sa karagdagang impormasyon at katanungan, maaring mag-*email* sa info@fda.gov.ph. Upang mag-*report* ng patuloy na pagtitinda o pangangalakal ng mga pekeng gamot, mag-*email* sa report@fda.gov.ph. Maaari ring tumawag sa *Center for Drug Regulation and Research* 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://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH> at kumpletuhin ang mga kinakailangang impormasyon.

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


DR. SAMUEL A. ZACATE
Director General

DTN:



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