



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. 2024-0500

07 MAR 2024

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT : Public Health Warning Against the Purchase and Use of the Counterfeit Drug Product “Valium® (Diazepam) 10 mg/2 mL Solution for Injection I.M./I.V. 5 ampoules of 2 mL”

The Food and Drug Administration (FDA) advises the public against the purchase and use of the counterfeit version of the following product:



AUTHENTIC

10 ampoules of 2 mL

Diazepam

Valium®

5 mg/mL (10mg/2mL)

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

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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Diazepam
Valium®
5 mg/mL (10mg/2mL)
Solution for Injection
072026

DR-6298 © = Reg. Phil. Pat. Off.

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

Counterfeit – The batch numbers and labeling requirements are not comparable with the standard features of the registered product.

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

Figure 1. Comparison between the Authentic and Verified Counterfeit Valium® (Diazepam) 10 mg/2 mL Solution for Injection I.M./I.V. 5 ampoules of 2 mL (Batch Nos. 101067 and 99375)

All healthcare professionals and the general public are hereby warned as to the availability of this counterfeit drug product in the market which pose potential danger or injury to consumers. Consumers are also reminded to purchase drug product only from FDA-licensed establishments.

Likewise, all establishments and outlets are hereby warned against selling and/or dispensing of the said counterfeit product with the abovementioned features. The importation, selling or offering for sale of such is in direct violation of 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. Anyone found selling the said counterfeit drug product will be penalized.

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. 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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