



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2016-068**

27 JUN 2016

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Use of the Unregistered Drug Product “Neurobion coated Tablets” of Merck KGaA & Co. Spittal, Austria

The Food and Drug Administration (FDA) advises the public against the use of the following unregistered drug product which has a registered counterpart brand “Neurobion coated Tablet”:



Figure 1: Unregistered Drug Product “Neurobion coated Tablet” of Merck KGaA & Co. Spittal, Austria.



Figure 2: Registered Drug Product Neurobion Tablet (Registration Number: DR-XY31882) Manufactured by PT Merck Indonesia Tbk



These unregistered "Neurobion coated Tablets" were found to be distributed in the Philippine market without approval of the FDA. Likewise, these were confirmed by the Marketing Authorization Holder (MAH), Merck, Inc. to be manufactured in Austria and intended for Malaysia.

All healthcare professionals and the general public are hereby warned to be vigilant of the abovementioned unregistered drug product with registered counterpart brand. This poses potential danger or injury to the consuming public and 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.

In the interest of protecting public health and safety, the Officers of the Field Regulatory Operations Office (FROO) are hereby mandated to exercise their regulatory function pursuant to Section 14 of Republic Act No. 9711.

All establishments and outlets are hereby warned against selling and/or dispensing the above identified drug product. Anyone found selling the said drug product will be penalized.

Likewise, all local government units and law enforcement agencies are requested to ensure that this drug product is not sold or offered for sale in their localities or area of jurisdiction.

All consumers are advised to purchase their medications only from FDA-licensed establishments. Please note that, in addition to inspection of establishments, product evaluation, registration, and testing are measures that the government undertakes to ensure the quality, safety, and efficacy of health products. Please look for the FDA Registration number on the product label. Moreover, please be reminded that drug products registered with FDA Philippines bear in their labels information in English and/or in Filipino for all consumers to understand.

The FDA registered Vitamins B1 + B6 + B12 (Neurobion) Tablet is manufactured by PT Merck Indonesia Tbk – Jl. T.B. Simatupang No. 8, Pasar Rebo, Jakarta 13760, Indonesia and imported by Merck, Inc. – 24/F GT Tower International, 6813 Ayala Ave. cor. H.V. Dela Costa St., Salcedo Village, Makati City


The blister label of Vitamins B1 + B6 + B12 (Neurobion) Tablet bears the following:

1. Generic Name
2. Expiry Date in every 2 Tablets

Vitamins B1 + B6 + B12 (Neurobion) Tablet is categorized as Vitamins. It is available in Alu Foil HSL/PVC-PVDC Blister x 10's (Box of 100's).

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 report@fda.gov.ph or you may call the telephone number (02)807-8275. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: www.fda.gov.ph/adr-report-new and fill out all the required fields.

Dissemination of the information to all concerned is requested.


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