



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2023-1590**

03 JUL 2023

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT : Public Health Warning Against the Purchase and Use of the Counterfeit Drug Product “Purified Rabies Vaccine [Vero Cell] (Speeda) 2.5 I.U. and 0.5 mL of solvent Freeze-dried Powder for Injection Intramuscular / Intradermal (I.M./I.D.) Vaccine 5 Vials”

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



AUTHENTIC

5 Vials

PURIFIED RABIES VACCINE (VERO CELL)

SPEEDA

2.5 I.U. and 0.5 ml of solvent
 Freeze-Dried Powder for Injection
 Intramuscular / Intradermal (I.M. / I.D.)
VACCINE

FOR HUMAN USE

Rx

Manufactured by:
 Uoqing Chang Da
 Biotechnology Co., Ltd.
 No. 3, Xiangyin 2nd Avenue,
 Hangzhou, Zhejiang, China

Imported and Distributed by:
 Pharma Sunny International, Inc.
 400 South St., Ste. 1000, Raleigh,
 North Carolina, USA

FORMULATION:
 Each vial contains:
 Purified Rabies Vaccine Freeze-Dried 2.5 I.U.

INDICATIONS:
 The product can induce immunity against rabies virus in
 susceptible following immunization. It is used to prevent
 rabies in human.


STORAGE:
 Store at temperature between 2-8°C.

**ADVERSE EFFECTS / CONTRAINDICATIONS /
 PRECAUTIONS:**
 For complete information, see product insert.

CAUTION:
 Foods, Drugs, Devices and Cosmetics Act prohibits
 dispensing without prescription.

DOSEAGE:
 (For Complete product information, see product insert)
 For suggested adverse drug reactions, report to the
 FDA, www.fda.gov.

Batch No.: 20221009AX
 Mfg. Date: Sep. 18, 2021
 Exp. Date: Sep. 18, 2024
 Reg. No.: ER-669




COUNTERFEIT

5 Vials

PURIFIED RABIES VACCINE (VERO CELL)

SPEEDA

2.5 I.U. and 0.5 ml of solvent
 Freeze-Dried Powder for Injection
 Intramuscular / Intradermal (I.M. / I.D.)
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 PRECAUTIONS:**
 For complete information, see product insert.

CAUTION:
 Foods, Drugs, Devices and Cosmetics Act prohibits
 dispensing without prescription.

DOSEAGE:
 (For Complete product information, see product insert)
 For suggested adverse drug reactions, report to the
 FDA, www.fda.gov.

Batch No.: 20221009AX
 Mfg. Date: Jan. 07, 2022
 Exp. Date: Jan. 07, 2025
 Reg. No.: ER-669




Counterfeit – The visual & physical appearance are not comparable w/ the standard features of the registered product.

Figure 1. Comparison between the Authentic and Verified Counterfeit Purified Rabies Vaccine [Vero Cell] (Speeda) 2.5 I.U. and 0.5 mL of solvent Freeze-dried Powder for Injection Intramuscular / Intradermal (I.M./I.D.) Vaccine 5 Vials (Batch No. Vial: 202201009AX, Ampoule: 28220303-1)

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, or through the online reporting facility, **eReport**, at www.fda.gov.ph/ereport. 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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