



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. 2023-1590-A

03 JUL 2023

- PARA** : SA LAHAT NG HEALTHCARE PROFESSIONALS AT SA PUBLIKO
- PAKSA** : Babala sa Publiko tungkol sa Paggamit ng Beripikadong Pekeng Gamot na “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”

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



Management System
ISO 9001:2015



TUNAY / 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:
Liaoning Cheng De
Biotechnology Co., Ltd.
No. 7 Xingyuan St., Fushun
New District, Liaoning, China

Imported and Distributed by:
Pharmos-Sereno International, Inc.
46-A, Bldg. 3, 1st Floor, Westgate
Green-City 111A, Pasig City

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 temperatures 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.

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

Batch No.: 2021003418BY
Mfg. Date: Sep. 19, 2021
Exp. Date: Sep. 19, 2024
Reg. No.: BR-080




PEKE / 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.)
VACCINE

FOR HUMAN USE

Rx

Manufactured by:
Liaoning Cheng De
Biotechnology Co., Ltd.
No. 7 Xingyuan St., Fushun
New District, Liaoning, China

Imported and Distributed by:
Pharmos-Sereno International, Inc.
46-A, Bldg. 3, 1st Floor, Westgate
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**ADVERSE EFFECTS / CONTRAINDICATIONS /
PRECAUTIONS:**
For complete information, see product insert.

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

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

Batch No.: 20221009AX
Mfg. Date: Jan. 27, 2022
Exp. Date: Jan. 27, 2025
Reg. No.: BR-080




Peke/Counterfeit – Ang visual at physical appearance ay hindi tugma sa rehistradong gamot

Larawan 1. Paghahambing sa Tunay/Authentic at Peke/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)

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, o mag-report gamit ang aming *online reporting facility, eReport*, sa www.fda.gov.ph/ereport. 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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