



23 JAN 2023

FDA ADVISORY
No. **2023-0148**

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT : Public Health Warning Against the Purchase and Use of the Counterfeit Drug Product “Rabies Vaccine for Human Use (Purified Chick Embryo Cell) (VaxiRab N) ≥2.5IU Lyophilized Powder for Solution for IM/ID Injection, Diluent: Sterilised Water for Injections BP 1mL”

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

AUTHENTIC	
<p>Purified Chick Embryo Cell Culture Rabies Vaccine VaxiRab N ≥ 2.5 IU Lyophilized Powder for Solution for Injection (IM/ID)</p> <p>Rx</p> <p>Imported and Distributed By: Zydus Healthcare Philippines Inc. Unit 903 & 904, 9th Flr., Eco Tower, 32nd Street, Cor. 9th Avenue, Bonifacio Global City, Taguig, Philippines Manufactured by: Cadila Healthcare Limited, Plot No. 417, 419, 420, Sakinhej-Bavli N.H. No. 8A, Village-Moraya, Tal-Sanand, Dist. Ahmedabad-382 210, India Manufacturer of Diluent: Sovereign Pharma Pvt. Ltd., Nani Daman</p>	<p>Formulation: Each vial of lyophilized powder contains: Inactivated rabies virus (Pitman Moore Strain) Potency ≥2.5 IU Excipients: Gelatin, Human Albumin, Sucrose</p> <p>INDICATIONS Active immunization against rabies</p> <p>Diluent: 1ml Sterilised Water for Injections BP FOR I.M./I.D. USE ONLY Reconstitute with accompanying diluent. For IM injection use immediately after reconstitution and for ID injection store at 2-8°C after reconstitution. Unused vaccine must be discarded after 6 hours or at the end of immunization session, whichever comes first. Dosage: For I.M. administration, use 1 full dose (1ml) for pre- and post-exposure as per WHO regime. For I.D. administration, use 0.1 ml per site for post-exposure as per WHO regime.</p> <p>The pack contains one vial of VaxiRab N and one ampoule of 1ml Sterilised Water for Injections BP</p> <p>CAUTION Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.</p> <p>ADR REPORTING STATEMENT: For the suspected adverse drug reaction, report to the FDA: www.fda.gov.ph Seek medical attention immediately at the first sign of adverse drug reaction.</p> <p>STORE AT 2°C TO 8°C (36°F to 46°F) DO NOT FREEZE. PROTECT FROM LIGHT. Refer to package insert for complete prescribing information</p> <p>Mfg. Lic. No.: GVAC-1 BR. No.: BPP-071</p> <p style="text-align: right;">Zydus Cadila</p>
<p>Rabies Vaccine For Human Use (Purified Chick Embryo Cell) VaxiRab N ≥ 2.5 IU Lyophilized Powder for solution for IM/ID injection</p> <p>Rx</p> <p>Imported and Distributed By: Zydus Healthcare Philippines Inc. Unit 903 & 904, 9th Eco Tower, 32nd St, Cor. 9th Avenue, Bonifacio Global City, Taguig City, Philippines Manufactured by: Cadila Healthcare Limited Plot No. 417, 419, 420, Sakinhej-Bavli N.H. No. 8A, Village-Moraya, Tal-Sanand, Dist. Ahmedabad-382 210, India Manufacturer of Diluent: Sovereign Pharma Pvt. Ltd., Nani Daman</p>	<p>Formulation: After reconstitution, each dose (1ml) contains: Rabies vaccine purified chick embryo cell culture (Pitman Moore Wistar Strain) Potency ≥ 2.5 IU Excipients: Gelatin, Human Albumin, Sucrose</p> <p>INDICATIONS Active immunization against rabies</p> <p>Diluent: 1ml Sterilised Water for Injections BP FOR I.M./I.D. USE ONLY Reconstitute with accompanying diluent. For IM injection use immediately after reconstitution and for ID injection store at 2-8°C after reconstitution. Unused vaccine must be discarded after 6 hours or at the end of immunization session, whichever comes first. Dosage: For I.M. administration, use 1 full dose (1ml) for pre- and post-exposure as per WHO regime. For I.D. administration, use 0.1 ml per site for post-exposure as per WHO regime.</p> <p>The pack contains one vial of VaxiRab N and one ampoule of 1ml Sterilised Water for Injections BP</p> <p>CAUTION Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.</p> <p>For the suspected adverse drug reaction, report to the FDA: www.fda.gov.ph Seek medical attention immediately at the first sign of adverse drug reaction.</p> <p>STORE AT 2°C TO 8°C (36°F to 46°F) DO NOT FREEZE. PROTECT FROM LIGHT. Refer to package insert for complete prescribing information</p> <p>Mfg. Lic. No.: GVAC-1 BR. No.: BPP-071</p> <p style="text-align: right;">Zydus Cadila</p>

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

Figure 1. Comparison between the Authentic and Verified Counterfeit Rabies Vaccine for Human Use (Purified Chick Embryo Cell) (VaxiRab N) ≥2.5IU Lyophilized Powder for Solution for IM/ID Injection, Diluent: Sterilised Water for Injections BP 1mL (Vial: RV100020, Ampoule: AMU1010)



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

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