



FDA ADVISORY

No. 2022-1575-A

06 SEP 2022

PARA : SA LAHAT NG HEALTHCARE PROFESSIONALS AT SA PUBLIKO

PAKSA : Babala sa Publiko tungkol sa Paggamit ng Beripikadong Pekeng Gamot na “Rabies Vaccine For Human Use (Purified Chick Embryo Cell) (VaxiRab N) \geq 2.5IU Lyophilized Powder for Solution for IM/ID Injection (Batch No. RV90016)”

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

TUNAY / AUTHENTIC

Purified Chick Embryo Cell Culture Rabies Vaccine
VaxiRab N
≥ 2.5 IU Lyophilized Powder for Solution for Injection (IM/ID)

Rx

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, Sankhe-Bavla N.H. No. 8A, Village-Moraya, Tal-Sanand, Dist. Ahmedabad-382 210, India
Manufacturer of Diluent
Sovereign Pharma Pvt. Ltd.,
Nani Damani

GTIN : 14806520081993
B.No. : RV90016
MFG. DATE : 19 SEP 22
SR.No. : P222C46XKCT

Formulation: Each vial of lyophilized powder contains: Inactivated rabies virus (Pitman Moore Strain) Potency 2.5 IU
Excipients: Gelatin, Human Albumin, Sucrose

INDICATIONS:
Active immunization against rabies

Diluent:
1ml Sterilized 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.

The pack contains one vial of VaxiRab N and one ampoule of 1ml Sterilized Water for Injections BP

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

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.

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

Mfg. Lic. No. : QVAC-1
BR. No. : BRP-071

**Zydus
Cadila**

RV20008
MAR. 22
FEB. 25

STERILIZED WATER INJECTIONS
FOR I.M. ADMINISTRATION, USE 1 ML 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.
DO NOT FREEZE. PROTECT FROM LIGHT.
Zydus Healthcare Limited
Plot No. 417, 419, 420, Sankhe-Bavla N.H. No. 8A, Village-Moraya, Tal-Sanand, Dist. Ahmedabad-382 210, India

PEKE / COUNTERFEIT

Rabies Vaccine For Human Use (Purified Chick Embryo Cell)
VaxiRab N
≥ 2.5 IU Lyophilized Powder for solution for IM/ID Injection

Rx

Imported and Distributed By:
Zydus Healthcare Philippines Inc.
Unit 903 & 904, 9th Flr., Eco Tower 32nd St. Cor. 9th Avenue, Bonifacio Global City, Taguig City, Philippines

Manufactured by:
Cadila Healthcare Limited
Plot No. 417, 419, 420, Sankhe-Bavla N.H. No. 8A, Village-Moraya, Tal-Sanand, Dist. Ahmedabad-382 210, India
Manufacturer of Diluent
Sovereign Pharma Pvt. Ltd.,
Nani Damani

GTIN : 14806520081990
B.No. : RV90016
MFG. DATE : 19 SEP 22
SR.No. : P222C46XKCT

Formulation: After reconstitution, each dose (1ml) contains: Rabies vaccine purified chick embryo cell culture (Pitman Moore Water Strain) Potency 2.5 IU
Excipients: Gelatin, Human Albumin, Sucrose

INDICATIONS:
Active immunization against rabies

Diluent:
1ml Sterilized 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.

The pack contains one vial of VaxiRab N and one ampoule of 1ml Sterilized Water for Injections BP

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

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

Mfg. Lic. No. : QVAC-1
BR. No. : BRP-071

**Zydus
Cadila**

RV90016
OCT. 19
SEP. 22

STERILIZED WATER INJECTIONS
FOR I.M. ADMINISTRATION, USE 1 ML 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.
DO NOT FREEZE. PROTECT FROM LIGHT.
Zydus Healthcare Limited
Plot No. 417, 419, 420, Sankhe-Bavla N.H. No. 8A, Village-Moraya, Tal-Sanand, Dist. Ahmedabad-382 210, India

Peke/Counterfeit – Ang batch number at label requirements ay hindi tugma sa rehistradong gamot.

Larawan 1. Paghahambing sa Tunay/Authentic at Peke/Counterfeit Rabies Vaccine For Human Use (Purified Chick Embryo Cell) (VaxiRab N) \geq 2.5IU Lyophilized Powder for Solution for IM/ID Injection (Batch No. RV90016).




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 gamut, 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: 

20220825102504