



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



10 JAN 2023

FDA ADVISORY
No. 2023-0057-A

PARA : SA LAHAT NG *HEALTHCARE PROFESSIONALS* AT SA PUBLIKO

PAKSA : Babala sa Publiko tungkol sa Paggamit ng mga sumusunod na Beripikadong Pekeng Gamot na:

1. **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.) 5 vials Anti-Rabies Serum (Equine) (Equirab) 200 IU/mL (1000 IU/5mL) Solution for Injection (I.M./S.C.)**

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



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 Da
Biotechnology Co., Ltd.
No.1 Xinfang St, Hulinan
New District, Shenyang, China.

Imported and Distributed by:
Pharma-Surrey International, Inc.
46 Bulacan St. Sta. Mesa Heights
Quezon City 1114, Philippines

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

INDICATIONS:
The product can induce immunity against rabies virus in recipients 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.

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

Batch No.: 202109341BY
Mfg. Date: Sep. 19, 2021
Exp. Date: Sep. 18, 2024
Reg.No.: BR-669




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 Da
Biotechnology Co., Ltd.
No.1 Xinfang St, Hulinan
New District, Shenyang, China.

Imported and Distributed by:
Pharma-Surrey International, Inc.
46 Bulacan St. Sta. Mesa Heights
Quezon City 1114, Philippines

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

INDICATIONS:
The product can induce immunity against rabies virus in recipients 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.

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

Batch No.: 202106207AY
Mfg. Date: 06/22/2021
Exp. Date: 09/01/2024
Reg. No.: BR-669




Peke/Counterfeit – Ang print appearance ay hindi tugma sa rehistradong gamot.

Larawan 1. Paghahambing sa Tunay/Authentic at Peke/Counterfeit na Purified Rabies Vaccine (Vero Cell) Speeda 2.5 I.U. and 0.5 mL of Solvent Freeze Dried Powder for Injection Intramuscular / Inradermal (I.M./I.D.) 5 vials (Lot No. 202106207AY,28210309-1)

TUNAY/AUTHENTIC

5 mL Vial


ANTI-RABIES SERUM (EQUINE)

EQUIRAB
200 IU/mL (1000 IU/5mL)
Solution for Injection (I.M./S.C.)

Imported by:
BSV Bioscience Philippines Inc.
Unit 3805 One San Miguel Ave. Condominium,
San Miguel Avenue Corner Shaw Boulevard Pasig,
Metro Manila, Philippines, 1600

Distributed by:
NEW MARKETLINK PHARMACEUTICAL CORP.
Two Corporate Center, 90 P.E. Antonio Street, Brgy.,
Ugong, Pasig City, Philippines, 1604

Manufactured by:
BHARAT SERUMS AND VACCINES LIMITED
K-27, Jambhvi Village,
Anand Nagar,
Additional M.I.D.C.,
Ambarnath (E),
Maharashtra, INDIA



BATCH NO.: (01) 18904012433629 (17) 240131
(10) A06822006
(21) BSL E000A14381144DP
MFG. DATE: A06822006
02/2022
EXP. DATE: 01/2024



FORMULATION
Each mL contains:
Anti-Rabies Serum (Equine) 200 I.U.

INDICATION
Equine Anti-Rabies Serum provides passive immunization against rabies. For prevention of rabies in patients at risk of being exposed to rabies after contact with a rabid animal or animal presumed to be rabid. Equine Anti-Rabies Serum itself does not constitute an Anti-Rabies treatment and should always be used in conjunction with rabies vaccine.

DOSAGE & ADMINISTRATION
See package insert for full information.

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

STORAGE CONDITION
Store at temperatures between 2°C to 8°C. Do not freeze.

PLEASE SEE PACKAGE INSERT FOR MORE INFORMATION.
MFG. LIC. NO. : KD-4
D.R. NO. : BR - 676



PEKE/COUNTERFEIT

5 mL Vial


ANTI-RABIES SERUM (EQUINE)

EQUIRAB
200 IU/mL (1000 IU/5mL)
Solution for Injection (I.M./S.C.)


Imported by:
BSV Bioscience Philippines Inc.
Unit 3805 One San Miguel Ave. Condominium,
San Miguel Avenue Corner Shaw Boulevard Pasig,
Metro Manila, Philippines, 1600

Distributed by:
NEW MARKETLINK PHARMACEUTICAL CORP.
Two Corporate Center, 90 P.E. Antonio Street, Brgy.,
Ugong, Pasig City, Philippines, 1604

Manufactured by:
BHARAT SERUMS AND VACCINES LIMITED
Plot No. K-27,
Anand Nagar,
Additional M.I.D.C.,
Ambarnath (East),
Maharashtra, India



BATCH NO.: (01) 18904012433629 (17) 240331
(10) A06822010
(21) BSL E000A2756674YZU
MFG. DATE: A06822010
04/22
EXP. DATE: 03/24



FORMULATION
Each mL contains:
Anti-Rabies Serum (Equine) 200 I.U.

INDICATION
Equine Anti-Rabies Serum provides passive immunization against rabies. For prevention of rabies in patients at risk of being exposed to rabies after contact with a rabid animal or animal presumed to be rabid. Equine Anti-Rabies Serum itself does not constitute an Anti-Rabies treatment and should always be used in conjunction with rabies vaccine.

DOSAGE & ADMINISTRATION
See package insert for full information.

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

STORAGE CONDITION
Store at temperatures between 2°C to 8°C. Do not freeze.

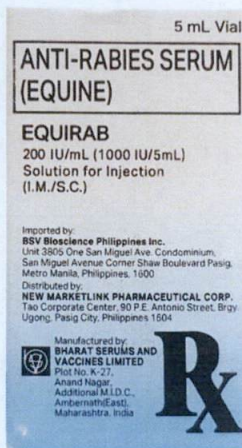
PLEASE SEE PACKAGE INSERT FOR MORE INFORMATION.
MFG. LIC. NO. : KD-4
D.R. NO. : BR - 676



Peke/Counterfeit – Ang batch number at print appearance ay hindi tugma sa rehistradong gamot.

Larawan 2. Paghahambing sa Tunay/Authentic at Peke/Counterfeit na Anti-Rabies Serum (Equine) (Equirab) 200 IU/mL (1000 IU/5mL) Solution for Injection (I.M./S.C.) (Batch No. A06822010)

PEKE/COUNTERFEIT



FORMULATION
Each mL contains:
Anti-Rabies Serum (Equine) 200 IU.

INDICATION
Equine Anti-Rabies Serum provides passive immunization against rabies. For prevention of rabies in patients at risk of being exposed to rabies after contact with a rabid animal or animal presumed to be rabid. Equine Anti-Rabies Serum itself does not constitute an Anti-Rabies treatment and should always be used in conjunction with rabies vaccine.

DOSAGE & ADMINISTRATION
See package insert for full information.

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

STORAGE CONDITION
Store at temperatures between 2°C to 8°C. Do not freeze.

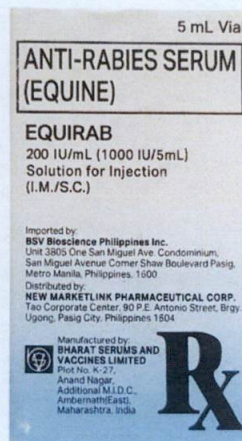
PLEASE SEE PACKAGE INSERT FOR MORE INFORMATION.

MFG. LIC. NO. : KD-4
D.R. NO. : BR - 676



Peke/Counterfeit – Ang batch number at *print appearance* ay hindi tugma sa rehistradong gamot.

PEKE/COUNTERFEIT



FORMULATION
Each mL contains:
Anti-Rabies Serum (Equine) 200 IU.

INDICATION
Equine Anti-Rabies Serum provides passive immunization against rabies. For prevention of rabies in patients at risk of being exposed to rabies after contact with a rabid animal or animal presumed to be rabid. Equine Anti-Rabies Serum itself does not constitute an Anti-Rabies treatment and should always be used in conjunction with rabies vaccine.

DOSAGE & ADMINISTRATION
See package insert for full information.

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

STORAGE CONDITION
Store at temperatures between 2°C to 8°C. Do not freeze.

PLEASE SEE PACKAGE INSERT FOR MORE INFORMATION.

MFG. LIC. NO. : KD-4
D.R. NO. : BR - 676



Peke/Counterfeit – Ang batch number at *print appearance* ay hindi tugma sa rehistradong gamot.

Larawan 3 at 4. Paghahambing sa Tunay/*Authentic* at Peke/*Counterfeit* na Anti-Rabies Serum (Equine) (Equirab) 200 IU/mL (1000 IU/5mL) Solution for Injection (I.M./S.C.) (Batch No. A02721016, A02721012, A02721009)


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 gamut, 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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