









FDA ADVISORY
No. **20230991**

18 MAY 2023

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT : Public Health Warning Against the Purchase and Use of the Counterfeit Drug Product “Anti-Rabies Serum (Equine) (Equirab) 200 IU mL (1,000 IU/5 mL) Solution for Injection (I.M./S.C.) 5 mL”

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

AUTHENTIC			
<p>5 mL Vial</p> <p>ANTI-RABIES SERUM (EQUINE)</p> <p>EQUIRAB 200 IU/mL (1000 IU/5mL) Solution for Injection (I.M./S.C.)</p> <p>Imported by: BSV Bioscience Philippines Inc. Unit 3805 One San Miguel Ave. Condominium, San Miguel Avenue Corner Shaw Boulevard Pasig, Metro Manila, Philippines, 1600</p> <p>Distributed by: NEW MARKETLINK PHARMACEUTICAL CORP. Two Corporate Center, 90 P.E. Antonio Street, Brgy. Ugong, Pasig City, Philippines, 1604</p> <p>Manufactured by: BHARAT SERUMS AND VACCINES LIMITED K-27, Jambhava Village, Anand Nagar, Additional M.I.D.C., Ambernath (E), Maharashtra, INDIA</p> 	<p>EXP. DATE: 01/2024</p> <p>MFG. DATE: 02/2022</p> <p>BATCH NO.: A06822006</p> <p>(01) 189804012433629 (17) 240131 (10) A06822006 (21) BSL E000A14381144DP</p> 	<p>FORMULATION Each mL contains: Anti-Rabies Serum (Equine) 200 I.U.</p> <p>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.</p> <p>DOSAGE & ADMINISTRATION See package insert for full information.</p> <p>CAUTION Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.</p> <p>STORAGE CONDITION Store at temperatures between 2°C to 8°C. Do not freeze.</p> <p>PLEASE SEE PACKAGE INSERT FOR MORE INFORMATION.</p> <p>MFG. LIC. NO. : KD-4 D.R. NO. : BR - 676</p>	
COUNTERFEIT			
<p>5 mL Vial</p> <p>ANTI-RABIES SERUM (EQUINE)</p> <p>EQUIRAB 200 IU/mL (1000 IU/5mL) Solution for Injection (I.M./S.C.)</p> <p>Imported by: BSV Bioscience Philippines Inc. Unit 3805 One San Miguel Ave. Condominium, San Miguel Avenue Corner Shaw Boulevard Pasig, Metro Manila, Philippines, 1600</p> <p>Distributed by: NEW MARKETLINK PHARMACEUTICAL CORP. Two Corporate Center, 90 P.E. Antonio Street, Brgy. Ugong, Pasig City, Philippines 1604</p> <p>Manufactured by: BHARAT SERUMS AND VACCINES LIMITED Plot No. K-27, Anand Nagar, Additional M.I.D.C., Ambernath (East), Maharashtra, India</p> 	<p>EXP. DATE: 06/24</p> <p>MFG. DATE: 07/22</p> <p>BATCH NO.: A06822030</p> <p>(01) 189804012433629 (17) 240630 (10) A06822030 (21) BSL E000A8828236WJX</p> 	<p>FORMULATION Each mL contains: Anti-Rabies Serum (Equine) 200 I.U.</p> <p>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.</p> <p>DOSAGE & ADMINISTRATION See package insert for full information.</p> <p>CAUTION Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.</p> <p>STORAGE CONDITION Store at temperatures between 2°C to 8°C. Do not freeze.</p> <p>PLEASE SEE PACKAGE INSERT FOR MORE INFORMATION.</p> <p>MFG. LIC. NO. : KD-4 D.R. NO. : BR - 676</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 Anti-Rabies Serum (Equine) (Equirab) 200 IU mL (1,000 IU/5 mL) Solution for Injection (I.M./S.C.) 5 mL (Batch No. A06822030)



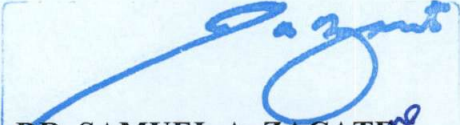
All healthcare professionals and the general public are hereby warned as to the availability of this counterfeit drug product in the market which pose potential danger or injury to consumers. Consumers are also reminded to purchase drug product only from FDA-licensed establishments.

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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