

FDA ADVISORY
No. 20240753

08 MAY 2024

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 (1000 IU/5mL) Solution for Injection (I.M./S.C.) 5 mL Vial”

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



AUTHENTIC

(01)18904012433629 (17)250430
 (10)A06823015
 (21)BSLE000A120358LA9

BATCH NO.: A06823015
 MFG. DATE: 05/2023
 EXP. DATE: 04/2025



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.

ADR REPORTING STATEMENT
 For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph. Seek medical attention immediately at the first sign of any adverse drug reaction.

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



COUNTERFEIT

(01) 18904012433629 (17) 250131
 (10) A06823006
 (21) BSLE000A92594784YQ

BATCH NO.: A06823006
 MFG. DATE: 02/23
 EXP. DATE: 01/25



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.

ADR REPORTING STATEMENT
 For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph. Seek medical attention immediately at the first sign of any adverse drug reaction.

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



Counterfeit – The batch number and print appearance 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 (1000 IU/5mL) Solution for Injection (I.M./S.C.) 5 mL Vial (Batch No. A06823006, Expiry date 01/25)

COUNTERFEIT



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.

ADR REPORTING STATEMENT
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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



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

Figure 2. Verified Counterfeit Anti-Rabies Serum (Equine) (Equirab) 200 IU/mL (1000 IU/5mL) Solution for Injection (I.M./S.C.) 5 mL Vial (Batch No. A06823007, Expiry date 01/25)

COUNTERFEIT



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.

ADR REPORTING STATEMENT
For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph. Seek medical attention immediately at the first sign of any adverse drug reaction.

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

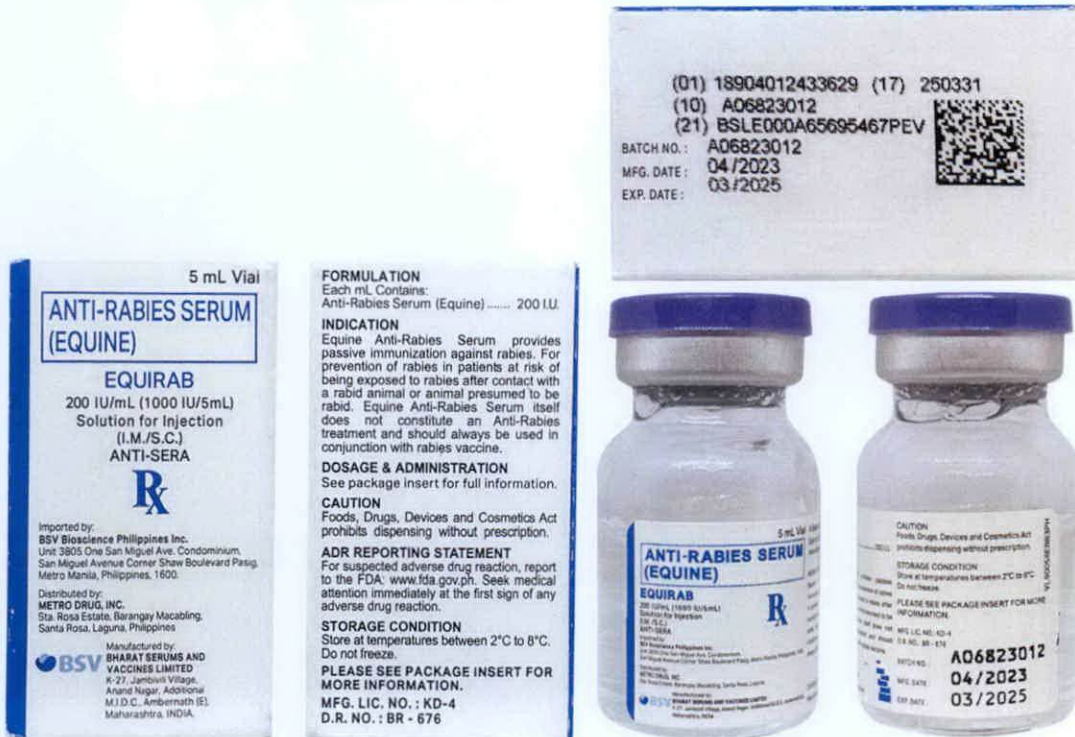
PLEASE SEE PACKAGE INSERT FOR MORE INFORMATION.
MFG. LIC. NO. : KD-4
D.R. NO. : BR - 676



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

Figure 3. Verified Counterfeit Anti-Rabies Serum (Equine) (Equirab) 200 IU/mL (1000 IU/5mL) Solution for Injection (I.M./S.C.) 5 mL Vial (Batch No. A06823011, Expiry date 02/2025)

COUNTERFEIT



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

Figure 4. Verified Counterfeit Anti-Rabies Serum (Equine) (Equirab) 200 IU/mL (1000 IU/5mL) Solution for Injection (I.M./S.C.) 5 mL Vial (Batch No. A06823012, Expiry date 03/2025)

COUNTERFEIT



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

Figure 5. Verified Counterfeit Anti-Rabies Serum (Equine) (Equirab) 200 IU/mL (1000 IU/5mL) Solution for Injection (I.M./S.C.) 5 mL Vial (Batch No. A06823014, Expiry date 04/2025)

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. 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://bit.ly/FDAPHReportSideEffect> 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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