REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

PUBLIC ALERT

FALSIFIED SIMULECT (BASILIXIMAB) FOR INJECTION, BATCH NO. SFYD2

The Pharmacy and Poisons Board ("the Board") is mandated by Cap 244 of the Laws of Kenya to protect and promote public health by regulating the pharmacy profession and ensuring access to quality, safe, and effective health products and technologies ("HPTs").

In furtherance of this mandate, the Board undertakes post-marketing surveillance activities to monitor HPTs circulating in the market and to take appropriate regulatory actions in safeguarding public health.

During the course of these surveillance activities, **the Board received an alert from the World Health Organization (WHO) regarding falsified SIMULECT (basiliximab) reported in Rwanda, Bulgaria, and Türkiye**. The falsified product displays a batch number of **SFYD2**, which is not a valid batch number for SIMULECT.

The falsified product label displays the National Drug Code NDC 0078-0331-84. While the National Drug Code (NDC) is a unique identifier for medicines marketed in the United States of America, the label contains other discrepancies compared to genuine SIMULECT packaging as follows;

1. The genuine product lists the ingredient dose in milligrams using "mg," while the **falsified product uses "MG"**.
2. The genuine product lists the country of manufacture as "Product of France" while **the falsified product lists the country of manufacture as "Product of Switzerland or France"**.

The falsified batch may contain incorrect, insufficient, or harmful ingredients, and its quality, safety, and efficacy cannot be guaranteed. Use of this product poses a serious risk to patient safety and public health

PUBLIC ADVISORY

To date, the Board has not detected or confirmed the presence of the falsified SIMULECT (basiliximab) batch SFYD2 within the Kenyan market. This alert is therefore issued as a **precautionary measure** to enhance vigilance, prevent potential entry into the supply chain, and safeguard public health. In light of the above, the Board advises as follows:

1. Procurement agencies, hospitals, distributors, pharmacists, pharmaceutical technologists, and members of the public are urged **to remain vigilant and report immediately any encounter with the falsified product batches.**
2. All stakeholders within the supply chain to procure HPTs exclusively from licensed manufacturers, importers, distributors, and retailers. Procuring from unlicensed sources endangers patients and constitutes a violation of the Pharmacy and Poisons Act, Cap 244 of the Laws of Kenya.

The Board, together with relevant Government investigative agencies, will take firm regulatory and legal action against any individual or entity involved in the distribution of this and any other falsified batches of HPTs.

HOW TO REPORT

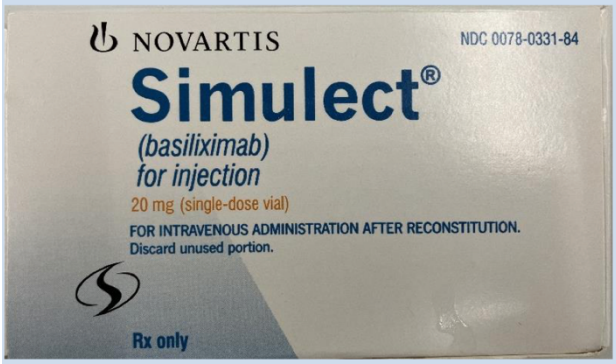
Any suspected falsified or substandard medicine, should be reported through the following official channels:

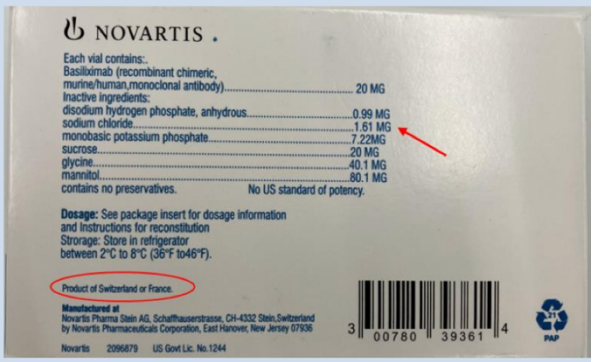
- Online portal: https://pv.pharmacyboardkenya.org/users/mpublic
- USSD Code: *271#
- Mobile App: mPvERS (Android & iOS)
- Email: pv@ppb.go.ke | pms@ppb.go.ke
- Telephone: 0795743049

The Pharmacy and Poisons Board remains committed to protecting and safeguarding public health. Your cooperation is essential in ensuring the quality, safety and efficacy of Health Products and Technologies in Kenya.

Dr. Ahmed I. Mohamed
Ag. CHIEF EXECUTIVE OFFICER
24th December 2025

PRODUCT PHOTO





Falsified SIMULECT vials