DRUG REGULATORY AUTHORITY OF PAKISTAN
Division of Quality Assurance and Laboratory Testing

RAPID ALERT

DRAP ALERT No: Nº I/S/12-25-121

Falsified SIMULECT (Basiliximab) for injection identified in the WHO African and European Regions

Date: 10th December, 2025

Target Audience:

- Regulatory Field Force of DRAP and Provincial Drug Control departments.
- Healthcare Professionals
- Consumers

Problem Statement:

This WHO Medical Product Alert refers to falsified **SIMULECT 20mg (basiliximab) for injection - batch number SFYD2**. The falsified product has been detected in **Rwanda, Bulgaria, and Türkiye,** and was reported to WHO in December 2024 and November 2025.

In Pakistan, **SIMULECT 20 mg (Reg. # 025218)** is supplied as a powder vial with or without a water for injection (solvent) ampoule for reconstitution, by **Novartis Pharma (Pakistan) Limited (Importer)**, and is administered either as an intravenous infusion or as an injection, usually in a hospital setting.

The genuine manufacturer also identified several visual discrepancies on the packaging & Batch number. The falsified product shows batch number **SFYD2**, which is not a valid batch number for **SIMULECT.** A sample of the falsified product was forensically tested by the genuine manufacturer and found to contain no active pharmaceutical ingredients; instead, it contained ascorbic acid.

Any **SIMULECT** product with batch number **SFYD2** should be considered falsified. 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.

- The genuine product lists the ingredient dose in milligrams using “mg,” while the falsified product uses “MG”.
- 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”.

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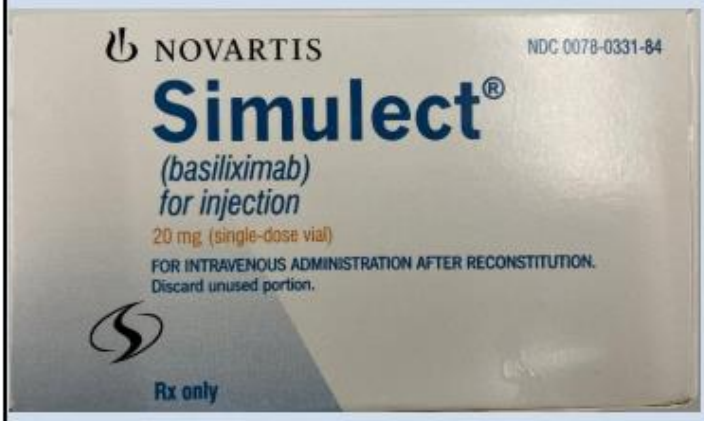
Annex: Product subject of WHO Medical Product Alert N°6/2025

Product Name	SIMULECT (basiliximab) for injection		
Stated manufacturer	NOVARTIS		
Identified in	Bulgaria	Rwanda	Türkiye
Batch number	SFYD2		
Expiry date	04 2027		

Available Photographs



Falsified SIMULECT vials

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Risk Statement:

This falsified product should be considered unsafe, and its use may pose severe and potentially life-threatening risks to patients, including:

- Therapeutic failure leading to organ rejection.
- Inadequate or excessive immune suppression, increasing vulnerability to opportunistic infections.
- Life-threatening allergic or toxic reactions from unknown or harmful ingredients.
- Risk of infection from unsterile injections. It is important to detect and remove any falsified SIMULECT from circulation to prevent harm to patients.

Action Initiated: -

The Regulatory Field Force of DRAP and Provincial Drug Control Departments has been directed to conduct surveillance activities throughout the supply chain to confiscate the falsified products.

Advice for Healthcare Professionals: -

DRAP requests healthcare professionals to have increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by above mentioned product. Any adverse events or quality problems experienced with the use of these products should be reported to National or Provincial pharmacovigilance centers using Adverse Event Reporting Form or online through this link. Further information on reporting problems to DRAP is available on this link.

Advice for Consumers:

Consumers should not use these products and should contact their physician or healthcare provider(s) if they have experienced any problem related to taking or using the above mentioned products and should report the incident to the Drug Regulatory Authority of Pakistan / National Pharmacovigilance Centre. All therapeutic goods must be obtained from licensed pharmacies and other authorized/licensed retail outlets. The authenticity and condition of products should be carefully checked. Seek advice from your pharmacists or other healthcare professionals in case of any doubt.

Drug Regulatory Authority of Pakistan

محفوظ، موثر اور معیاری اشیائے علاج

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