



DRUG REGULATORY AUTHORITY OF PAKISTAN

Division of Quality Assurance and Laboratory Testing

RAPID ALERT

DRAP ALERT No: N° I/S/07-26-37

Falsified DARZALEX (Daratumumab) Injection Identified in WHO Regions of the Americas and South-East Asia

Date: 16th July, 2026

Target Audience:

- National Regulatory Field Force of DRAP and Provincial Drug Control Departments.
- Healthcare Professionals (Oncologists, Hematologists, Pharmacists & Nurses).
- Hospitals and Oncology Treatment Centres.
- General Public.

Problem Statement:

The Drug Regulatory Authority of Pakistan (DRAP) has received a **Medical Product Alert No. 3/2026** issued by the **World Health Organization (WHO)** regarding **falsified DARZALEX (Daratumumab) Injection** identified in the WHO Regions of the Americas and South-East Asia. The falsified products were detected in **Maldives** and **Mexico** after being supplied through **non-authorized distributors**, with at least one report indicating supply to hospitals.

The genuine manufacturer, **JANSSEN**, has confirmed that the following batch numbers are **not valid** and any DARZALEX product bearing these batch numbers should be considered **falsified**.

S#	Name of Product	Batch No.	Stated Manufacturer	Remarks
1	DARZALEX (Daratumumab) Injection 400 mg/20 mL	STV1K01	Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, Belgium.	Falsified Product
2	DARZALEX (Daratumumab) Injection 100 mg/5 mL	MYS7381		Falsified Product

Risk Statement:

DARZALEX (daratumumab) is a monoclonal antibody indicated for the treatment of **multiple myeloma** and **amyloid light-chain (AL) amyloidosis**.

No laboratory testing has been performed on the falsified products and their **identity, composition, quality, and sterility remain unknown**. These products may contain **no active ingredient, incorrect ingredients, or harmful substances**, making them ineffective or potentially dangerous.

WHO has also reported the presence of **visible particulate matter** in one falsified batch (STV1K01), indicating a potential risk of contamination. Use of these products may result in treatment failure, disease progression, infections, injection-related complications, increased morbidity, and potentially life-threatening outcomes.



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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

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