World Health Organization

3 July 2026

Medical Product Alert N°3/2026
Falsified DARZALEX (daratumumab) identified in the WHO regions of the Americas and South-East Asia

Alert Summary

This WHO Medical Product Alert concerns two batches of falsified DARZALEX (daratumumab) injection. The falsified products were detected in Maldives and Mexico. National Regulatory Authorities in both countries reported the incidents to WHO in May and June 2026. The falsified products were supplied or offered by non-authorized distributors and, in at least one case, hospitals received these falsified products.

DARZALEX is a medicine (monoclonal antibody) used to treat rare blood disorders and cancers that affect bone marrow, specifically multiple myeloma and amyloid light-chain (AL) amyloidosis.

How to identify these falsified products

These products are considered falsified because they deliberately misrepresent their identity, composition, or source. The genuine manufacturer, JANSSEN, has confirmed that the batch numbers on the falsified products, MYS7381 and STV1K01, are not valid. Any DARZALEX product with these batch numbers should be considered falsified and not used. The Maldives Food and Drug Authority reported visible particulate matter in vials of falsified DARZALEX, batch STV1K01.

Risks

Falsified DARZALEX (daratumumab) poses a serious risk to patient safety. No laboratory testing has been conducted on these products. Their contents, quality, and sterility remain unknown. They may contain no active ingredient. They may contain the wrong ingredients, or harmful substances. As a result, these products may be ineffective or harmful.

Visible particulate matter was found in at least one falsified batch, STV1K01. This signals a risk of contamination. Patients could face adverse reactions, including infections or injection-related complications.

Patients receiving falsified DARZALEX may not get appropriate treatment for their condition. This can lead to disease progression. It can also increase morbidity and mortality. Prompt detection and removal of these products from the supply chain is essential to prevent patient harm.

Advice to health-care professionals, regulatory authorities and the public

Health-care professionals should report any unusual adverse events; unexpected lack of therapeutic effects or observed quality defects associated with DARZALEX to their National Regulatory Authority or National Pharmacovigilance Centre or WHO at the email below.

WHO advises increased surveillance and monitoring of the supply chain in countries and regions likely to be affected by these falsified products. Increased surveillance of the informal/unregulated market, including online platforms, is especially advised. National regulatory authorities, health authorities, and law enforcement should notify WHO immediately if these products are detected.

If you have these products, do not use them. If you, or someone you know, has, or may have used these products, or suffered an adverse event or unexpected side-effect after use, seek immediate medical advice from a health-care

professional. All medical products must be obtained from authorized/licensed suppliers. If you have any information about the manufacture or supply of these products, please contact WHO via rapidalert@who.int.

Annex: Products subject of WHO Medical Product Alert N°3/2026

Product name	DARZALEX (daratumumab) Injection 400 mg/20mL	DARZALEX (daratumumab) Injection 100 mg/5 mL
Batch	STV1K01	MYS7381
Expiry	05 2029	03 2029
Identified in	Maldives	Mexico
Stated manufacturer	JANSSEN	
Available Photographs		

Batch STV1K01 identified Maldives