Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عمان
وزارة الصحة
مركز سلامة الدواء
مسقط

To:
Pharmacist Incharge, Armed Forces Hospital (AT Khoudh & Salalah)
Director of Pharmaceutical Care, Royal Hospital
Director of Pharmaceutical Care, Khoula Hospital
Pharmacist Incharge, Al Nahda Hospital
Director of Pharmaceutical Care, DGHS, Muscat Governorate
Director of Pharmaceutical Care, DGHS, Al Dakhliya Governorate
Director of Pharmaceutical Care, DGHS, South Batinah Governorate
Director of Pharmaceutical Care, DGHS, North Batinah Governorate
Director of Pharmaceutical Care, DGHS, AI Dhahira Governorate
Director of Pharmaceutical Care, DGHS, North Sharqiya Governorate
Director of Pharmaceutical Care, DGHS, South Sharqiya Governorate
Director of Pharmaceutical Care, DGHS, Musandam Governorate
Director of Pharmaceutical Care, DGHS, Dhofar Governorate
Director of Pharmaceutical Care, DGHS, Al Wusta Governorate
Director of Pharmaceutical Care, DGHS, Buraimi Governorate
Director of Pharmaceutical Care, DGMS
Pharmacist Incharge, Al Massarah Hospital
HOD, Pharmacy Department, Sultan Qaboos University Hospital
Pharmacist Incharge, Royal Oman Police
Pharmacist Incharge, The Diwan
Pharmacist Incharge, The Sultan's Special Force
Pharmacist Incharge, Internal Security Services
Pharmacist Incharge, Petroleum Development of Oman
Pharmacist Incharge, LNG Oman

After Compliments,

Kindly find attached our Circular No. 71 **dated** 6 **/07/2026 Regarding Alert to Health Care Professionals About Falsified DARZALEX (daratumumab).**

Copy to:

- **Director of Pharmacovigilance Department, DSC**
- **Director of Medicine Registration Department, DSC**
- **Director of Regulatory Compliance Department, DSC**
- **Director of Central Quality Control Lab., DSC**
- **Director of Medical Device Department, DSC**
- **Section Head of Medicine Safety Evaluation**
- **Section Head of Quality Problems and Medication Errors.**
- **Section Head of Pharmacovigilance**
- **Section Head of Clinical Trials**

DSC
مركز سلامة الدواء
Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

Circular No. 71 /2026

20 -1-1448 H

06 -07-2026

Subject: Falsified DARZALEX (daratumumab) Injection 400 mg/20ml & 100 mg/5 ml

The Drug Safety Center (DSC) would like to share a safety alert information published by **world health organization (WHO)** regarding Falsified Darzalex (Daratumumab) Injection 400 mg/20ml & 100 mg/5 ml.

Darzalex is a prescribed only medication in Oman used to treat rare blood disorders and cancers that affect bone marrow, specifically multiple myeloma, and amyloid light-chain (AL) amyloidosis.

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. (attachment1)

Risk of using falsified Darzalex (Daratumumab):

- 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.

DSC مركز سلامة الدواء Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

Advice for Healthcare Professionals to Provide to Patients:

- 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, pharmacovigilance department.
- 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.
- 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.

Call to Report:

Darzalex (daratumumab) is registered in Oman. All health care professional, patient and caregiver are requested to report any falsified products or adverse drug effect to Ministry of Health e-portal TO Pharmacovigilance Department Under Drug Safety Center.

Ph. Ibrahim Nasser Al Rashdi
Director General

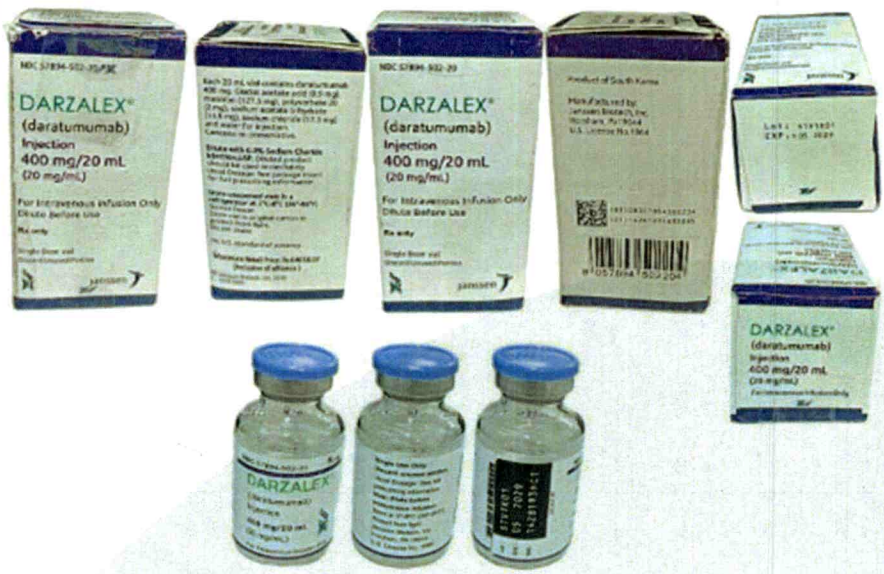
DSC
مركز سلامة الدواء
Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

Attachment 1:

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



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om