# Medical Product Alert Notice on Falsified IMFINZI (durvalumab) Injection 500mg/10ml

## Medical Product Alert No; 06/ 2025

**Picture of Falsified Product**


The Ethiopia Food and Drug Authority is mandated by article 38 Food and medicine administration proclamation 1112/2019 to performe periodic monitoring of the safety, quality and efficacy of medicine through survilance.

### Alert Summary

The WHO Incidents and Substandard/Falsified Medical Products (ISF) Team's medicinal product alert notification refers to one batch of falsified IMFINZI (durvalumab) injection 500mg/10ml stated manufacturer AstraZeneca.As per WHO medical product Alert the falsified products have been detected in the unregulated supply chain in Armenia, Lebanon and Türkiye. Laboratory analysis of samples of the falsified IMFINZI have been carried out by AstraZeneca. The analysis confirmed that the vials of the falsified product contained no active pharmaceutical ingredient.

### Brief Description of the Product

IMFINZI (durvalumab) injection 500mg/10ml.

Batch No. BAVX, Manufacture date: 10/2021 and 10/2023

Expire Date: 9/2026 and 9/2024

Stated manufacturer: Astrazenica

### How to identify this falsified product

From WHO Medical product aler website https://www.who.int/health-topics/substandard-and-falsified-medical-products notification which indicate:

These products are falsified because they deliberately misrepresent their identity, composition, and source.

## To identify these falsified products, check for the following:

• Genuine IMFINZI lot BAVX, is associated with the manufacturing date of 10-2021 and an expiry date of 09-2024.

• A combination of any other dates or lot number should be considered suspicious.

• The 2D data matrix is displayed in the middle instead of the upper-right of the box.

The face where the 2D data matrix, lot number, manufacturing and expiry dates are displayed should be in black and white, not totally black.

• The rectangle, displaying the strength of the medicine, should be in a paler green colour rather than dark green.

• The metal crimp of the closure around the neck of the vial should not be creased.

## Risks Summary

These falsified products should be considered unsafe, and their use may be life threatening in some circumstances. The use of these falsified IMFINZI products may lead to ineffective or delayed treatment. It is important to detect and remove any falsified IMFINZI (durvalumab) injections from circulation so as to prevent harm to patients.

## Target Audiences

The authority intends to alert health care providers about the need to detect and remove circulation and administration/use of falsified medicinal product to prevent harm to patients.

Advice to regional regulatory authorities, healthcare professionals, and Public

The authority also intends to alert the regional regulatory authority to monitor the circulation and use of falsifiedd product. If you have this falsified medicinal product, please do not use it or any one you know have you used this product or suffered any adverse reaction/event after use you are advice to seek immediate medical advice from aqualified health care professional.

## Report Adverse Events

The EFDA encourages members of the public and health care providers to report any suspicious, substandard, or falsified medical products to the Ethiopia Food and Drug Authority through ADE reporting form, Med safety mobile apps available at play store for androids and app store for iPhone, E-reporting available on EFDA website (www.efda.gov.et),Through email pharmacovigilance @efda.gov.et and Toll-free number 8482.

Alert

# Picture of Falsified Product

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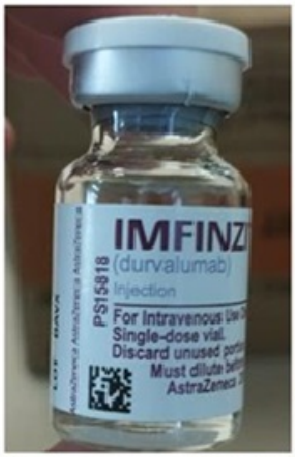
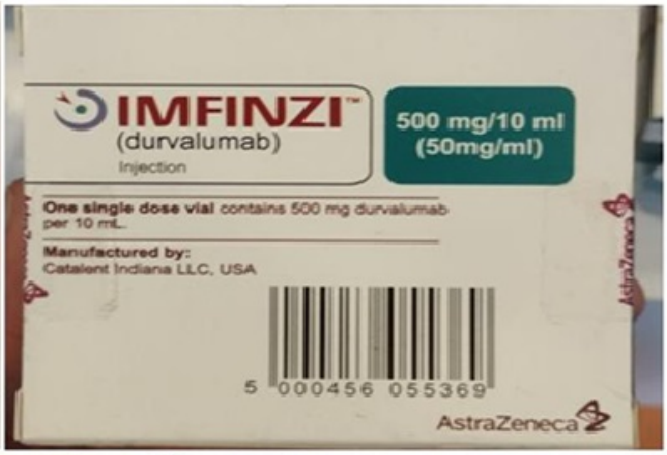
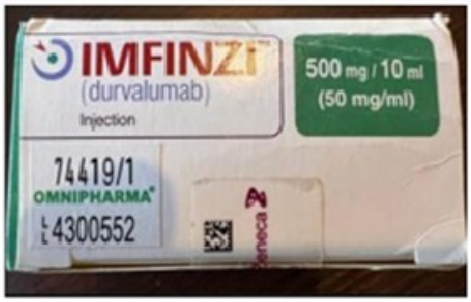
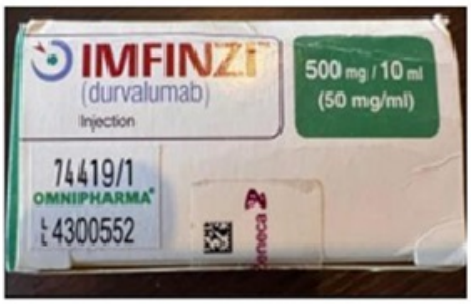
|---|---|---|---|
| **Product Name** | IMFINZI (durvalumab) injection 500mg/10ml | | |
| **Stated manufacturer** | AstraZeneca | | |
| **Identified in** | Armenia | Lebanon | Türkiye |
| **Lot** | BAVX | BAVX | BAVX |
| **Manufacturing date** | 10-2023 | 10-2021 | 10-2021 |
| **Expiry date** | 09-2026 | 09-2024 | 09-2024 |
| **Available photos** |             | | |