



DRUG REGULATORY AUTHORITY OF PAKISTAN

Division of Quality Assurance and Laboratory Testing

RAPID ALERT

DRAP ALERT No: N° I/S/07-26-38

Falsified JAKAVI® (Ruxolitinib) Tablets Identified in the WHO Eastern Mediterranean and European Regions

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 **WHO Medical Product Alert No. 2/2026** regarding **falsified JAKAVI® (ruxolitinib) tablets** identified in the WHO Eastern Mediterranean and European Regions. The falsified products were detected in the **Islamic Republic of Iran, Türkiye, and the Russian Federation** after being illicitly sold through online platforms and, in at least one instance, supplied through a pharmacy.

The genuine manufacturer, **Novartis Pharma AG**, has confirmed that the following batch numbers are **not genuine**. Any JAKAVI® product bearing these batch numbers should be considered **falsified** and should not be used.

S#	Name of Product	Batch No.	Manufacturer Details	Remarks
1	JAKAVI® (Ruxolitinib) Tablets 20 mg	AVT50	Manufacturer: Novartis Pharma AG, Lichtstrasse 35, CH-4056 Basel, Switzerland	Falsified Product
2	JAKAVI® (Ruxolitinib) Tablets 15 mg	FNR06	Manufacturer: Novartis Pharma AG, Lichtstrasse 35, CH-4056 Basel, Switzerland	
3	JAKAVI® (Ruxolitinib) Tablets 15 mg	SGL04	Manufacturer: Novartis Pharma AG, Lichtstrasse 35, CH-4056 Basel, Switzerland	

Risk Statement:

JAKAVI® (ruxolitinib) is indicated for the treatment of **myelofibrosis, polycythaemia vera, and graft-versus-host disease following stem cell transplantation**.

The identified products are **falsified medical products**. Novartis has confirmed that the above-mentioned batch numbers are not valid. Laboratory analysis of a sample from batch **AVT50** confirmed the **absence of the declared active ingredient (ruxolitinib)**. Additionally, visual discrepancies were identified in the packaging, including the absence of batch numbers on blister strips of certain falsified batches.

Use of these falsified products may result in treatment failure, disease progression, increased morbidity, and potentially life-threatening outcomes. Patients receiving JAKAVI® often have compromised immune systems, making them particularly vulnerable to ineffective or falsified medicines.



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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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