



# DRUG REGULATORY AUTHORITY OF PAKISTAN

## Division of Quality Assurance and Laboratory Testing

### RAPID ALERT

DRAP ALERT No: N° I/S/09-25-66

#### Falsified Vigamox® Ophthalmic Solution - Batch VHF02A (Not from Authorized Source)

**Date:** 17<sup>th</sup> September, 2025

**Target Audience:**

- Regulatory Field Force of DRAP and Provincial Drug Control departments.
- Healthcare Professionals
- Consumers

**Problem Statement:**

Novartis Pharma (Pakistan) Ltd., Karachi informed DRAP that falsified **Vigamox®** Sterile Ophthalmic Solution bearing **Batch # VHF02A** is identified in the Pakistani market. The reported batch number is not imported, manufactured, or supplied by **Novartis Pharma (Pakistan) Ltd.**, i.e. the genuine registration holder in Pakistan. The packaging falsely uses the Novartis name and branding, but it does not come from the authorized supply chain.

**Risk Statement:**

In the case of **Vigamox® (Batch No. VHF02A)**, such falsification may result in ineffective treatment of bacterial eye infections, potential worsening the infection, and risk of serious eye damage or vision loss. **This alert applies only to Batch No. VHF02A** and does not affect other batches of Vigamox® in the market supplied by the authorized registration holder. The falsified batch poses a particular risk to patients with eye infections, especially children, the elderly, and those with weakened immune systems, who may experience rapid deterioration if untreated or improperly treated.

**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.



DRAP, Islamabad

+ 92 051 9255969

gsms@dra.gov.pk

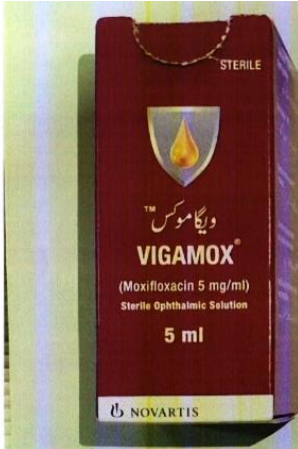


# DRUG REGULATORY AUTHORITY OF PAKISTAN

## Division of Quality Assurance and Laboratory Testing

### Pictorial Identification Guide — Genuine vs Falsified Product: -

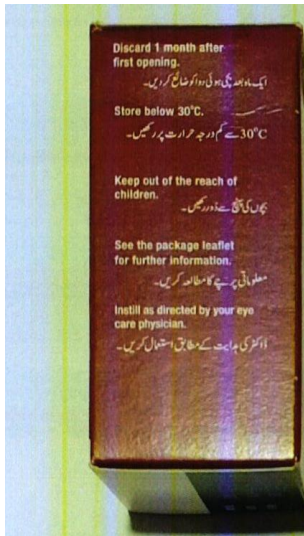
ORIGINAL



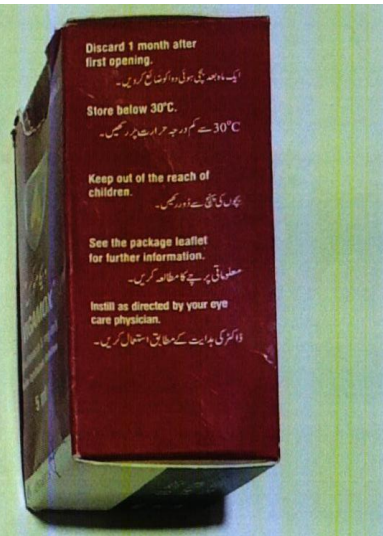
FALSIFIED



ORIGINAL



FALSIFIED



DRAP, Islamabad



+ 92 051 9255969



gsms@dra.gov.pk



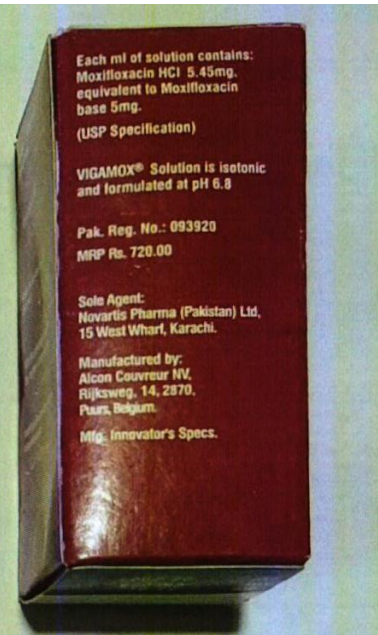
# DRUG REGULATORY AUTHORITY OF PAKISTAN

## Division of Quality Assurance and Laboratory Testing

ORIGINAL



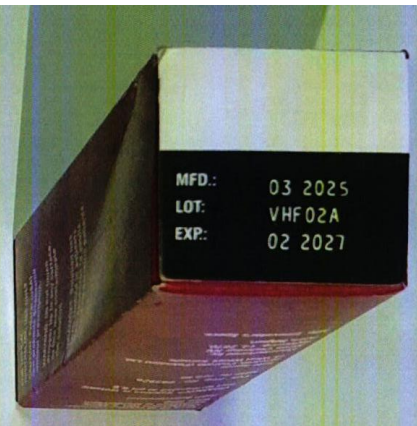
FALSIFIED



ORIGINAL



FALSIFIED



DRAP, Islamabad



+ 92 051 9255969



gsms@dra.gov.pk



# DRUG REGULATORY AUTHORITY OF PAKISTAN

## Division of Quality Assurance and Laboratory Testing

**ORIGINAL**

**FALSIFIED**



### **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**

محفوظ، موثر اور معیاری اشیائے علاج

