# MEDICAL PRODUCT ALERT

**DRAP ALERT NO.** Nº I/S/06-25-49

## Recall of Substandard "Famobex Suspension" Batch No. 5330, Manufactured by M/s Cibex (Pvt.) Ltd, Karachi.

**Date:** 23rd June, 2025

**Target Audience:**

- National Regulatory Field Force of DRAP and Provincial Drug Control Departments.
- Healthcare Professionals (Physicians, Pharmacists & Nurses).
- General Public.

**Alert Summary:**

Federal Government Analyst, CDL, Karachi vide test report No. KQ-2-25-000015 has declared the sample of subject mentioned batch of the product as of '***Substandard***' quality. Details of the CDL test report are as under:

| S. No. | Product | Manufactured by | Batch No. | CDL Test Result |
|---|---|---|---|---|
| 1. | **Famobex Suspension**<br>Each 5ml contains:<br>Famotidine.….10mg<br><br>Reg# 027108 | **M/s Cibex (Private) Limited.,**<br>F-405, S.I.T.E, Karachi. | 5330 | **'Substandard'** on the basis of Assay Test. |

**Risk Statement:**

The use of substandard products can result in therapy failure, increasing the risk of complications, particularly in vulnerable groups such as immunocompromised individuals, as well as pediatric and geriatric population.

**Action initiated: -**

The field force of DRAP and Provincial Drug Control departments have been directed to immediately conduct market surveys for detection of presence and removal of mentioned batches from the market.

**Advice for Pharmacies/Medical stores: -**

All pharmacists and chemist working at distributions and pharmacies should **immediately check** their stocks and stop supplying mentioned products. The remaining stocks should be quarantined and returned to the supplier/company. Regulatory field force of all federating units (DRAP and Provincial Health Departments) should also increase surveillance in the market to ensure the effective recall of defective products(s).

**Advice for Healthcare Professionals: -**

DRAP requests increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by batches of mentioned products. Adverse reactions or quality problems experienced with the use of above mentioned product are to be reported to the National Pharmacovigilance Centre (NPC), DRAP using Adverse Event Reporting Form or online through this link. Further information of reporting problems to DRAP is available on this link.

**Advice for Consumers/general public: -**

Consumers should stop using products bearing the affected batch number(s) and shall contact to their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product, and report the incident to Drug Regulatory Authority of Pakistan/ National Pharmacovigilance Centre.

**Drug Regulatory Authority of Pakistan**
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