PRODUCT RECALL ALERT

DRAP ALERT NO. Nº II/S/08-23-31

RECALL OF KEMYGYL SUSPENSION 200MG/5mL (Batch # M-319)

(MANUFACTURED BY M/S. ALKEMY PHARMACEUTICAL LABORATORIES (PVT) LTD, HYDERABAD)

Date: 8th Sep, 2023

Target Audience:

- Pharmacists and Chemists at Distribution, Pharmacies and Medical Stores
- Healthcare Professionals- Physicians, Pharmacists, and Nurses at hospital and clinics etc.
- General Public

Alert Summary:

The Provincial Government Analyst/Director, Drug Testing Laboratory, Karachi has declared the Batch No. M-319 of Kemygyl Suspension as of **substandard** quality sampled by Provincial Inspector of Drugs Jamshoro.

The detail of the product is as under:

Product Name	**Composition**	**Batch No.**	**Manufactured by**	**Remarks**
Kemygyl Suspension 200mg/5ml	Metronidazole	**Batch No. M-319** Mfg. Date: 09-2022 Exp. date: 08-2024	Ms. Alkemy Pharmaceutical Laboratories (Pvt.) Ltd, Hyderabad.	The sample is of Sub-standard quality on the basis of assay which does not comply with acceptance criteria.

Risk Statement:

Metronidazole Oral Suspension is indicated in the prophylaxis and treatment of infections in which anaerobic bacteria have been identified or suspected. Use of substandard products may lead to suboptimal to no-therapeutic effects and may contribute to drug resistance, and can also intensify/exacerbate the existing bacterial infection.

Action Initiated: -

The manufacturing company has been directed to immediately recall the defective batch of product from the market. All pharmacists and chemists working at distributions and pharmacies should **immediately check** their stocks and stop supplying this batch of product. The remaining stock should be quarantined and returned to the supplier/ company. The 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 to enhance **vigilance** within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by these defective lot/batch of product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the National Pharmacovigilance Centre(NPC), DRAP using the 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 this product 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 the National Pharmacovigilance Centre of Drug Regulatory Authority of Pakistan, through MedSafety Mobile Application, or online at Med Vigilance E Reporting System.

All therapeutic goods must be obtained from licensed pharmacies and other authorized retail outlets. The authenticity and condition of products should be carefully checked. Seek advice from your pharmacists or other healthcare professional in case of any doubt.

Drug Regulatory Authority of Pakistan
محفوظ، موثر اور معیاری اشیائے علاج

DRAP, Islamabad | 92 51 9107404 | gsms@dra.gov.pk