PRODUCT RECALL ALERT

DRAP ALERT NO. Nº II/S/09-23-38

RECALL ALERT OF KEMODRYL COUGH SYRUP (Batch # K-1068)

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

Date: 16th October, 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:

Federal Government Analyst, CDL Karachi has declared the Batch No. L083 of product "Kemodryl Cough Syrup" as of **substandard** quality.

The detail of the affected product is as under:

Product Name	Composition	Batch	Manufactured by:	Remarks of CDL
Kemodryl Cough Syrup Reg.No 007069	Chlorpheniramine Maleate 4mg: Ammonium Chloride 125mg : Sodium Citrate 55mg	Batch No. K-1068 Mfg. Date: Aug 2023 Exp. Date: July 2025	Ms. Alkemy Parmaceutical Laboratories (Pvt) Ltd., Hyderabad.	The sample is of Sub-standard quality for non-complying assay criteria for sodium citrate.

Risk Statement:

Kemodryl Cough Syrup is a combination of Chlorpheniramine Maleate + Ammonium Chloride + Sodium Citrate which relieves cough. Chlorpheniramine is an anti-allergic which relieves allergy symptoms like runny nose, watery eyes and sneezing. Ammonium chloride can be used as an expectorant due to its irritative action on the bronchial mucosa. Sodium citrate is a mucolytic.

Inaccurate use of the product may lead to common side effects like Stomach pain/epigastric pain, Allergic reaction, sleepiness, thickened respiratory tract secretions and impaired coordination.

The impact of the use of substandard products on the basis of a higher limit of assay tests may cause adverse reactions on therapeutic doses.

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Action Initiated: -

The manufacturer 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) have also increased 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 this affected batch of product.

Adverse reactions or quality problems experienced with the use of this product should 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 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 Drug Regulatory Authority of Pakistan/ National Pharmacovigilance Centre, through MedSafety Mobile Application, or online at Med Vigilance E Reporting System.

All therapeutic goods must be obtained from the 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، موئثر اور معیاری اشیائے علاج

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