MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/2-25-22

VOLUNTARY RECALL OF ALL BATCHES OF LACOLEP INJECTION 10MG/ML MANUFACTURED BY M/S HILTON PHARMA, KARACHI.

Date: 25th February, 2025

Target Audience:

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

Alert Summary:

The firm M/s Hilton Pharma (Pvt) Ltd, Karachi, has informed Drug Regulatory Authority of Pakistan regarding voluntary recall of all marketed batches of Lacolep Injection 10mg/ml (Reg # 076086), due to the concerns regarding deviations in the quality parameters of certain batches of the aforementioned drug. In connection with this, the firm has published a public notice in the leading newspaper, ***The News-Jang***, advising all distributors and dealers to return their stocks in hand to their nearest distributors and/or directly to the company.

S#	Product Name	Composition	Batch No.	Manufacturers
1.	**Lacolep Injection 10mg/mL** Reg. No. 076086	Lacosamide	All marketed batches	**M/s. Hilton Pharma Pvt. Ltd.** Plot 13 & 14, Sector 15, Korangi Industrial Area, Karachi.

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 under administrative control of DRAP and Provincial Drug Control departments have been directed to immediately conduct market surveys for detection of presence and removal of all the batches of mentioned drug 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 all the batches of mentioned product. 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 the mentioned product. 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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