PRODUCT RECALL ALERT

DRAP ALERT NO. Nº I/S/09-23-32

RECALL OF PEDOLIL 250MG/5ML SUSPENSION (BATCH # 167)

(MANUFACTURED BY M/S. JASM PHARMACEUTICAL (PVT) LTD., RISALPUR)

Date: 18th 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:

Federal Government Analyst, CDL Karachi has declared the Batch No. 167 of product 'Pedolil Suspension" as of **substandard** quality.

The detail of the product is as under:

Product Name	Composition	Batch Detail	Manufactured by	Remarks
Pedolil 250mg/5mL Suspension Reg No. 110389	Paracetamol (Acetaminophen)	**Batch No. 167** Mfg. Date: 05-2023 Exp. Date: 04-2025	Ms. JASM Pharmaceutical (Pvt.) Ltd., Risalpur	The sample is of Sub-standard quality on the basis of non-complying deliverable volume.

Risk Statement:

Paracetamol suspension is used for mild to moderate pain and fever. Inaccurate use of the product may lead to adverse reactions including but not limited to following:

- Blood disorders, such as thrombocytopenia and leukopenia.
- Liver and kidney damage.

Impact of use of substandard product on basis of deliverable volume may leads to non- uniformity of dose and may alter therapeutic effect.

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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 the 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
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