PRODUCT RECALL ALERT

DRAP ALERT NO. Nº II/S/03-23-19

RECALL OF MEFCO 50mg/5mL SUSPENSION (Batch # 2J041)
(MANUFACTURED BY M/s. EROS PHARMACEUTICALS (PVT) LTD., KARACHI)

Date: 29th March 2023.

Target Audience:

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

Alert Summary:

Federal Government Analyst, CDL Karachi has declared the Batch No. 2J041 of the product "MEFCO Suspension" as of **substandard** quality.

Detail of the product is as under:

Product Name	Composition	Manufactured by	Remarks
Mefco 50mg/5ml Suspension **Batch No. 2J041** Mfg. Date: 10-2022 Exp. date: 10-2024	Mefenamic Acid	Ms. Eros Pharmaceuticals (Pvt.) Ltd., Karachi	The sample is of Sub-standard quality on the basis of pH test. The result of pH test does not comply with acceptance criteria.

Risk Statement:

Mefenamic acid is used to treat mild to moderate pain. Impact of use of substandard product on basis of pH test may significantly altered the solubility and interfere with its absorption.

Action Initiated: -

The manufacturer has been directed to **immediately recall** the defected batch of product from the market. All pharmacists and chemist working at distributions, pharmacies and other authorized retail outlets should **immediately check** their stocks and **stop** supplying this batch of product. The remaining stock should be quarantined and returned to the supplier/company. Regulatory field force of all federating units (DRAP, Provincial Health Departments and states) have also increased surveillance in the market to ensure the effective recall of defective products(s).

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Advice for Healthcare Professionals: -

DRAP requests to enhance **vigilance** within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by this defected 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 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 **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 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
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