MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/12-24-54

SUBSTANDARD NOCOX TABLETS BATCH NO. 8463

(MANUFACTURED BY M/S. ALFALAH PHARMA (PVT.) LTD., 12-KM LAHORE RD, JAMAL PARK, SHEIKHUPURA)

Date: 12th December, 2024.

Target Audience:

- Physicians, Pharmacists, Nurses and General Public.

Alert Summary:

Federal Government Analyst, CDL Karachi vide test report No. LHR-10-24-000007 has declared the subject mentioned batch of product Nocox tablet as of substandard quality. Details of CDL test report are as under

S.No	Product	Mfg. by	Batch No.	Mfg. / Exp.	CDL Test Result
01	Nocox Tablet Meloxicam 15mg/tab (Reg# 052499)	M/s. Alfalah Pharma (Pvt.) Ltd., 12-km Lahore Rd, Jamal Park, Sheikhupura	8463	02-2024 02-2026	Substandard on the basis of dissolution

Risk Statement:

Meloxicam is a nonsteroidal anti-inflammatory drug (NSAID) commonly used to reduce inflammation and pain in conditions such as arthritis. The identified quality issue with these tablets may result in Reduced Efficacy, depending on the degree of substandard quality and the patient's condition. Vulnerable populations, including elderly patients and those with existing gastrointestinal, cardiovascular, or renal conditions, may be at a higher risk.

Action initiated: -

The manufacturer has been directed to immediately recall the defected batches of mentioned products from the market. All pharmacists and chemist working at distributions and pharmacies are hereby advised to **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 DRAP and Provincial Health Departments are also informed regarding the matter and are directed to increase surveillance in the market to ensure the effective recall of defective products(s).

DRAP, Islamabad
92 51 9107404
addl-dir.qa@dra.gov.pk

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 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 Drug Regulatory Authority of Pakistan/ National Pharmacovigilance Centre.

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

DRAP, Islamabad
92 51 9107404
addl-dir.qa@dra.gov.pk