# MEDICAL PRODUCT ALERT

**DRAP ALERT NO.** Nº I/S/11-24-48

## RECALL OF NABAXO 10MG FILM COATED TABLET MANUFACTURED BY M/S. WENOVO PHARMACEUTICALS, TAXILA.

**Date:** 15th November, 2024.

### Target Audience:

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

### Alert Summary:

Senior Drug Inspector Islamabad has informed DRAP that batch number 263 of product namely Nabaxo 10mg film coated tablet has been declared as out of specifications by Drug Testing Laboratory Rawalpindi. Details of test reports are as under:

| S# | Product Name | Batch No. | Manufactured by | Test Results |
|---|---|---|---|---|
| 01 | Nabaxo 10mg film coated tablet (Reg. No. 087751) | 263 | M/s. Wenovo Pharmaceuticals, Plot No. 31, 32, Punjab Small Industrial Estate, Taxila. | Substandard and Misbranded |

### Risk Statement:

Nabaxo tablet contains Rivaroxaban is an anticoagulant medication used to treat and prevent blood clots. Rivaroxaban is used to treat deep vein thrombosis (blood clot, usually in the leg) and pulmonary embolism (blood clot in the lung) in adults. Substandard Rivaroxaban may lead to therapy failure in patients.

### Action initiated: -

The regulatory field force of DRAP and Provincial Drug Control departments have been directed to immediately conduct market surveys for detection and removal of these products from the market. All pharmacists and chemists working at distributions and pharmacies should immediately check their stocks and stop supplying these products. The remaining stocks should be quarantined and the information of their supplier should be immediately provided to their area drug inspector to ensure the removal of falsified product.

**Advice for Healthcare Professionals: -**

DRAP requests increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by batches of mentioned products. Adverse reactions or quality problems experienced with the use of these products 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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