MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/02-25-18

VOLUNTARY RECALL OF 36 BATCHES OF MOTIVAL TABLETS (REG # 004539) MANUFACTURED BY M/S GSK PAKISTAN LIMITED, KARACHI.

Date: 18th 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 GSK Pakistan Limited, Karachi has notified Drug Regulatory Authority of Pakistan that they have initiated **voluntary recall** of 36 batches of Motival Tablets due to the detection of nitrosamine impurity, N-nitroso nortriptyline. Moreover, the firm has reported that it has ceased the manufacture and release of Motival Tablets. The details of the recalled product lots are as follows:

S#	Product Name	Composition	Batch Numbers/lots	Manufactured by
01	Motival Tablets 5 × 20's (Reg # 004539)	Nortiptyline as HCl 10mg + Fluphenazine HCl 0.5mg	9P8L, A95S, A95Y, AN5N, AN5P, AN5R, AN5T, CK7G, CK7H, DT7B, DT7D, DL8J, DT7C, H58X, H58Y, H59A, J77W, J77V, K36F, K36E, KD6N, KD6P, M32F, ME8N, ME8R, R47H, R47K, R47L, SA7F, SA7G, SA6V, WM8R, WM8T, WM8U, YB7A, YB7B.	M/s. GSK Pakistan Limited, Plot # 5, Sector 21, Korangi Industrial Area, Karachi.

Risk Statement:

The risk of nitrosamine impurity in nortriptyline, like other pharmaceutical products, is a broader concern that became more prominent after several incidents. These impurities are believed to have carcinogenic potential in certain situations.

Action initiated: -

The field force under administrative control of DRAP and Provincial Drug Control departments have been directed to conduct market surveillance for detection of presence and removal of recalled batches 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 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 mentioned products. 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
محفوظ، موثر اور معیاری اشیائے علاج

DRAP, Islamabad
+92 051 9255969
gsms@dra.gov.pk