PRODUCT RECALL ALERT

DRAP ALERT NO. Nº II/S/02-24-09

RECALL OF DXL 60mg CAPSULE (BATCH NO. 23136)

(MANUFACTURED BY M/S. M/s. TITLIS PHARMA, RAIWIND ROAD, LAHORE)

Date: 27th February, 2024.

Target Audience:

- National Regulatory Field Force.
- Pharmacists and Chemists at Distribution, Pharmacies and Medical Stores
- Healthcare Professionals- Physicians, Pharmacists, and Nurses at hospital and clinics etc.

Alert Summary:

The Secretary, PQCB Baluchistan has reported that samples of "DXL 60mg Capsule" bearing Batch No. 23136 manufactured by M/s. M/s. Titlis Pharma, 528-A Sundar Industrial Estate, Raiwind Road, Lahore. has been declared as "**Substandard**" by Government Analyst, Drug Testing Laboratory, Baluchistan.

Details of the affected product is as under:

Product Name	**Composition**	**Batch Details**	**Manufactured by**	**Remarks**
DXL 60mg Capsule Reg.No 097679	Dexlansoprazole	**Batch No. 2336** Mfg. Date: 03-23 Exp. date: 03-25	M/s. Titlis Pharma, 528-A Sundar Industrial Estate, Raiwind Road, Lahore.	The sample is declared as of substandard quality on the basis of assay under the Drugs Act 1976.

Risk Assessment: -

The use of substandard dexlansoprazole capsules may lead to untoward adverse drug reactions and may generate an unpredictable response based on individual variability.

Action Initiated: -

The manufacturer has been directed by the Secretary PQCB Baluchistan to immediately recall the mentioned batch of product from the market. All pharmacists and chemist 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. 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).

DRAP, Islamabad | 92 51 9107404 | gsms@dra.gov.pk

-Distributors and pharmacies are advised to be vigilant and report any suspected batch of the product(s) in the supply chain to the DRAP using the **online form**, or through phone at +92 51 910 73 17, or by Email at gsms@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 products.

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 on 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 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

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