DRUG REGULATORY AUTHORITY OF PAKISTAN
DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº II/S/10-25-94

DRUG PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL DRUG TESTING LABORATORIES.

Date: 16th October, 2025

Target Audience:

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

Alert Summary:

Directorate of Drugs Control Punjab (DDCP) informed the Drug Regulatory Authority of Pakistan that the sample of below mentioned drug product has been declared as '***Substandard***'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**Kanabax Cream 15gm** Each Gram contains: Dexamethasone …… 1mg Neomycin sulphate …….. 3.5mg	KNX-272	M/s Baxter Pharmaceuticals. A-1/A Scheme No. 33 Phase-I S.I.T.E. Super Highway Karachi. (DML # 000700)	The sample is declared as **"misbranded"** with regards Labelling as per Section 3(s)(iv), **'adulterated'** with regards to Section 3(a)(iv) of the Drugs Act,1976 & **'substandard'** on the basis of Assay of Dexamethasone Phosphate.
2.	**Zysic Tablet 10 mg** Each film coated tablet contains: Cetirizine HCI (USP) ... 10mg	727	M/s Jinnah Pharmaceuticals (Pvt) Ltd. 13-Km Lahore Road Multan. (DML # 000578)	**'Sub-Standard'** with regards to Impurities Test.

Risk Statement:

Use of *Kanabax Cream (Batch No. KNX-272)*, declared **misbranded, adulterated, and substandard**, may lead to ineffective treatment, worsening of skin infections, or antimicrobial resistance, particularly in **children and patients with chronic skin conditions**. Similarly, *Zysic Tablet 10 mg (Batch No. 727)*, found **substandard due to impurities**, may cause reduced efficacy or mild adverse effects in **allergic or asthmatic individuals**. Consumers are advised to **avoid these batches and seek medical advice** if already used.

Action initiated: -

The field force of DRAP and Provincial Drug Control departments have been directed to immediately conduct market surveys for detection of presence and removal of mentioned batches from the market.

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

Advice for Pharmacies/Medical stores: -

All pharmacists and chemist working at distributions and pharmacies should **immediately check** their stocks and stop supplying mentioned products. 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