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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº II/S/10-25-101

DRUG PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL DRUG TESTING LABORATORIES

Date: 24th October, 2025

Target Audience:

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

Alert Summary:

Drug Testing Laboratory from Province informed that the sample of below mentioned drug products have been declared as '***Substandard***'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**Cream Kanadex-N** Each gram contains: Dexamethasone-21 phosphate in the form of disodium salt …… 1mg Neomycin in the form of sulphate……. 3500I.U (Reg.# 012475)	D7-22 & F7-27	M/s ISIS Pharmaceutical & Chemical Works. 25/1-3 Sector 12-C North Karachi Industrial Area Karachi. (DML # 000126)	The sample is declared **"Substandard"** on the basis of the **assay of Dexamethasone Phosphate (as disodium salt)**, and **"Adulterated"** on the basis of the **identification and quantification of Dexamethasone (base)** in HPLC analysis (**0.343 mg/g**), which is an **undeclared active pharmaceutical ingredient not stated on the product label.**

Risk Statement:

The presence of an undeclared corticosteroid, coupled with sub-therapeutic potency of the declared active ingredient, may lead to **unpredictable clinical outcomes**, including **reduced therapeutic efficacy**, **skin atrophy**, **hormonal disturbances**, or **systemic corticosteroid exposure**, especially with prolonged use.

Patients suffering from **eczema, dermatitis, and other inflammatory skin conditions**, as well as **children and individuals using topical steroids on large surface areas**, are the most likely to be affected. The use of this defective product undermines treatment safety and effectiveness and may result in **adverse dermatological or systemic effects**.

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.

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
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