PRODUCT RECALL ALERT

DRAP ALERT NO. Nº I/S/01-23-03

RECALL OF SANTODEX OPHTHALMIC OINTMENT (B. NO. BJ-082)
(MANUFACTURED BY M/S. SANTE (PRIVATE) LIMITED, KARACHI)

Date: **23rd January, 2023**

Target Audience:

- Pharmacists and Chemists at Distribution, Pharmacies and Medical Stores
- Healthcare Professionals- Physicians, Pharmacists, and Nurses at hospitals and clinics etc.
- General Public

Alert Summary:

Provincial Drug Inspector, Karachi collected the sample of Santodex Ophthalmic Ointment and sent for analysis. Federal Government Analyst, CDL Karachi has declared the Batch No. BJ-082 of product 'Santodex Ophthalmic ointment" as of substandard quality. Details of the product are given as under:

Product Name	**Composition**	**Manufactured by**	**Remarks**
Santodex Ophthalmic ointment **Batch No. BJ-082** Mfg. Date: 04-2022 Exp. date: 04-2024	Tobramycin 3mg/g and dexamethasone 1mg/g	Ms. Sante (Private) Limited, Karachi	The sample is of Sub-standard quality (on basis of assay test the result of which does not comply with acceptance criteria).

Action Initiated: -

The company has been directed to immediately recall the defected batch of product from the market. All Pharmacists and chemists working at distributions and Pharmacies should **immediately check** their stocks and stop supplying this batch of product. The remaining stock should be quarantine and return to the supplier / company. Regulatory field force of all federating units (DRAP, Provincial Health Departments and States) have also increased surveillance in the market to ensure the effective recall of defective product(s).

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 product.

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Adverse reactions or quality problems experienced with the use of this product may 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 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 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.

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