PRODUCT RECALL ALERT

DRAP ALERT NO. . Nº I/S/03-23-16

RECALL OF OPHTH-CARB STERILE INTRAOCULAR SOLUTION
(MANUFACTURED BY M/S. OPHTH PHARMA (PVT) LTD., KARACHI)

Date: 09th March 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:

Federal Government Analyst, CDL Karachi has declared the following product as of **substandard** quality.

Detail of the product is as under:

Product Name	**Composition**	**Manufactured by**	**Remarks**
Ophth-Carb Sterile Intraocular Solution **Batch No. OP154** Mfg. Date: 12-2022 Exp. date: 11-2024	Carbachol 0.1mg	Ms. Ophth Pharma (Pvt.) Ltd., Karachi	Sample does not comply Sterility testing as per USPNF 2022.

Risk Statement:

Carbachol is primarily used in the treatment of glaucoma, it is also used during ophthalmic surgery. All ophthalmic products must meet a number of requirements of safety and sterility and if the product is not sterile (free from bacteria or microorganisms), it may lead to serious infection which includes but not limited to redness of eyes, itching in eyes, watery discharge, blurred vision and loss of vision.

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Action Initiated: -

The manufacturer has been directed to **immediately recall** the defected 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).

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.

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.

Drug Regulatory Authority of Pakistan
محفوظ، موثر اور معیاری اشیائے علاج

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