DRUG REGULATORY AUTHORITY OF PAKISTAN
Division of Quality Assurance and Laboratory Testing

RAPID ALERT

DRAP ALERT No: Nº I/S/01-26-135

Unregistered, Substandard /Misbranded – OMNIVISC 2%

Date: 21st January, 2026

Target Audience:

- Regulatory Field Force of DRAP and Provincial Drug Control departments.
- Healthcare Professionals
- Consumers

Problem Statement:

Drug Testing Laboratory, Punjab informed that samples of the below-mentioned products have been found unregistered and declared **Substandard and Misbranded** under the Drugs Act, 1976 and Drugs (Labeling & Packing) Rules, 1986.

S#	Product Name	Batch No.	Manufacturer	Remarks
1.	Omnivisc 2% (HPMC) Ophthalmic Solution USP, 5 mL	OMV190171	***(purported to be manufactured by)*** M/s Omni Lens Pvt. Ltd., Plot No. 17, Ambota, Sector-5, Parwanoo Distt. Solan (H.P.), India	The sample has been declared **Substandard** on the basis of **failed sterility test (Non-sterile)** and **Misbranded** due to labeling discrepancies including mismatch of batch number on labels, absence of Pakistan Drug Registration Number, absence of Urdu instructions, and non-mentioning of maximum retail price.
2	Omnivisc 2% (HPMC) Ophthalmic Solution USP, 5 mL	OMV191171	***(purported to be manufactured by)*** M/s Omni Lens Pvt. Ltd., Plot No. 17, Ambota, Sector-5, Parwanoo Distt. Solan (H.P.), India	The sample has been declared **Substandard** on the basis of **failed sterility test (Non-sterile)** and **Misbranded** due to absence of Pakistan Drug Registration Number, incomplete labeling particulars including Urdu instructions and maximum retail price, in violation of Drugs Act, 1976 and Drugs (Labeling & Packing) Rules, 1986.

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Risk Statement:

The use of **Omnivisc 2% (HPMC) Ophthalmic Solution, Batches OMV190171 and OMV191171**, poses a **serious and vision-threatening public health risk** due to failure of **sterility testing**, rendering the product **non-sterile**, and due to **misbranding**. Ophthalmic preparations are required to be sterile, and the use of a non-sterile eye product may lead to **severe ocular infections**, including **conjunctivitis, keratitis, endophthalmitis**, corneal ulceration, and potential **irreversible loss of vision or blindness**. The absence of proper labeling information, including DRAP's Drug Registration Number and usage instructions in Urdu, increases the risk of **misuse, inappropriate dosing, prolonged use, and delayed medical intervention**. Patients undergoing eye surgery, those with corneal injuries, contact lens users, and immunocompromised individuals are at **particularly high risk**. Continued circulation and use of these batches may therefore result in **serious ocular morbidity**, warranting immediate regulatory action and strict removal from the supply chain.

Action Initiated: -

The Regulatory Field Force of DRAP and Provincial Drug Control Departments has been directed to conduct surveillance activities throughout the supply chain to recall these products.

Advice for Healthcare Professionals: -

Healthcare professionals, including ophthalmologists, general practitioners, pharmacists, and nursing staff, are advised to **exercise heightened vigilance** regarding the use and supply of **Omnivisc 2% (HPMC) Ophthalmic Solution, Batch Nos. OMV190171 and OMV191171**. They should **immediately discontinue prescribing, dispensing, or administering** these batches and ensure their **removal from institutional and retail inventories**. Patients who may have been exposed to these products should be **clinically evaluated for signs of ocular infection or adverse reactions**, particularly post-operative eye patients and contact lens users.

Any adverse events or quality problems experienced with the use of these products should be reported to National or Provincial pharmacovigilance centers using Adverse Event Reporting Form or online through this link. Further information on reporting problems to DRAP is available on this link.

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Advice for Consumers:

Consumers are strongly advised to **immediately stop using Omnivisc 2% (HPMC) Ophthalmic Solution**, particularly **Batch Nos. OMV190171 and OMV191171**, and to **check product labels and batch numbers carefully**. Any remaining stock should be **isolated and returned to the point of purchase** and not used further. Individuals who have already used these eye drops and experience symptoms such as **eye redness, pain, discharge, blurred vision, sensitivity to light, or worsening of eye condition** should seek **immediate medical attention from an ophthalmologist**. Patients who have recently undergone **eye surgery**, suffered **eye trauma**, or have underlying eye infections are at **higher risk** and should be especially vigilant. Consumers are also encouraged to **report the product and any suspected adverse effects** to the relevant health authority to help prevent further harm and protect public health.

Drug Regulatory Authority of Pakistan

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