



# DRUG REGULATORY AUTHORITY OF PAKISTAN

## DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING

### MEDICAL PRODUCT ALERT

DRAP ALERT NO. N° I/S/10-26-41

**DRUG PRODUCT DECLARED SUBSTANDARD & ADULTERATED BY CENTRAL DRUGS LABORATORY KARACHI.**

**Date:** 19<sup>th</sup> October, 2026

#### Target Audience:

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

#### Alert Summary:

Central Drugs Testing Laboratory, Karachi informed that the samples of diluent i.e. **Water for Injection** (Batch # W-174) in the combo-pack of the below mentioned drug products have been declared as '**Substandard**' based on presence of visible particles.

| Sr. No. | Product Name                | Batch Numbers                        | Manufacturers                                                                                                     |
|---------|-----------------------------|--------------------------------------|-------------------------------------------------------------------------------------------------------------------|
|         | Exoran-500mg Injection vial | P-240<br>P-239                       | M/s City Pharmaceutical Laboratories, Plot 12-A, I-5, Sector 5, Korangi Industrial Area, Karachi (DML No. 00723). |
|         | Exoran-1g Injection vial    | P-252<br>P-251                       | M/s City Pharmaceutical Laboratories, Plot 12-A, I-5, Sector 5, Korangi Industrial Area, Karachi (DML No. 00723). |
|         | Exit 500mg injection        | P-829<br>P-828                       | M/s City Pharmaceutical Laboratories, Plot 12-A, I-5, Sector 5, Korangi Industrial Area, Karachi (DML No. 00723). |
|         | Exit 1g injection           | P-1107<br>P-1106<br>P-1105<br>P-1104 | M/s City Pharmaceutical Laboratories, Plot 12-A, I-5, Sector 5, Korangi Industrial Area, Karachi (DML No. 00723). |

The details of Substandard water for injection are as follows:

| Sr. No. | Product Name        | Batch No. | Manufacturers                                                                                                     | Remarks                                                                                            |
|---------|---------------------|-----------|-------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
|         | Water for Injection | W-174     | M/s City Pharmaceutical Laboratories, Plot 12-A, I-5, Sector 5, Korangi Industrial Area, Karachi (DML No. 00723). | The sample has been declared as "Substandard" based on presence of particles visible to naked eye. |



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#### Risk Statement:

These findings indicate a **high public health risk**, primarily affecting **hospitalized patients and vulnerable groups**. The most likely to be harmed are **neonates, children, elderly patients, immunocompromised individuals, post-surgical patients, and those receiving IV therapy**. Substandard Water for injection containing particles visible to the naked eye may cause bloodstream infections, septic or pyrogenic reactions, and potentially fatal complications. Particles may also contribute to embolic or inflammatory complications. The greatest risk is in intensive care, emergency, and other clinical settings where sterile injectable products are essential.

#### 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 chemists working at distributions and pharmacies should **immediately check** their stocks and stop supplying mentioned products along with the other drug products containing **Water For Injection (Batch No.: W-174)**. 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 products along with the other drug products containing **Water For Injection (Batch No.: W-174)** are to be reported to the National Pharmacovigilance Centre (NPC), DRAP using Adverse Event Reporting Form or online through this [link](#). Further information about 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 containing water for injection (Batch No.: W-174) and shall contact to their physician or healthcare provider if they have experienced any problems that may be related to taking or using the drug products, and report the incident to Drug Regulatory Authority of Pakistan/ National Pharmacovigilance Centre.



Drug Regulatory Authority of Pakistan

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