RAPID ALERT

DRAP ALERT NO. Nº I/S/12-22-40

FALSIFIED PRODUCT ALERT

Date: 1st December, 2022

Target Audience:

- Regulatory Field Force
- Healthcare Professionals- Anesthesiologist, Surgeons, Pharmacists, and Nurses
- Pharmacists and Chemists at Distribution, Institutional suppliers
- General Public

Problem Statement:

During the surveillance activities in different Hospitals of Punjab, Regulatory Field Force had drawn samples of this product for test/analysis. The Provincial Drugs Testing Laboratory, Faisalabad has declared the samples as **spurious and adulterated**.
The product detail is as under: -

Product Name	**Purported to be Manufactured by (as stated on label)**	**Remarks by DTL**
RESTANE Inhalation Solution 100ml **Composition:** Isoflurane **Batch No.** N0111B24 N0892A10	**Manufactured by** M/s Piramal Critical Care, Inc. Schelden Circle Bethlehem PA 18017, USA **Marketed by** Allied Distributors 103-K, Block-2 P.E.C.H.S, Karachi Pakistan.	"The sample is **Spurious & Adulterated**" (as the active ingredient i.e. Isoflurane was not identified instead Chloroform was identified).

Action Initiated: -

The Regulatory Field Force has been directed to increase the surveillance activities at Health Facilities (Hospitals) in addition to markets and confiscate these batches of product. All Pharmacists and chemists working at Hospital distributions and Pharmacies should **immediately check** the stock and stop supplying these batches of product. The remaining stock should be quarantined immediately, and supplier's information should be provided to the Regulatory field force (DRAP, Provincial Health Departments and States) in order to ensure the removal of this products.

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Advice for Healthcare Professionals: -

DRAP requests increased vigilance at hospitals and within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by this product. Anesthesiologists and the supporting staff involved in surgical procedures where anesthetics are involved should remain vigilant about the suspected batches of said products.

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: -

If you are intending to plan any surgeries where anesthetic procedures are involved, or you are an attendant to a such patient, you are requested to cross check the originality of this product with your healthcare professionals (e.g. physicians, surgeons, gynecologist, anesthesiologist, etc.) to ensure the originality of product.

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