# RAPID ALERT

**DRAP ALERT No**: I/S/11-24-42

## FALSIFIED RHOPHYLAC 300MCG PFS, HUMAN ANTI-D IMMUNOGLOBULIN INJECTION IDENTIFIED IN MARKET

**Date:** 07th November, 2024

### Target Audience:

- Regulatory Field Force of DRAP and Provincial Drug Control departments.
- Healthcare Professionals
- Pharmacies and medical stores

### Problem Statement:

The firm M/s Hakimsons Impex (Private) Ltd, Karachi, has notified DRAP regarding the presence of falsified Rhophylac 300mcg PFS in the market across Pakistan and also referred to letter No. 438/PDI-ZR/PWR, received from Provincial Inspector, Peshawar for verification of the sample. The packaging of the product shows two different batch numbers while barcode scan displays another batch number. Details of the identified product is as under:

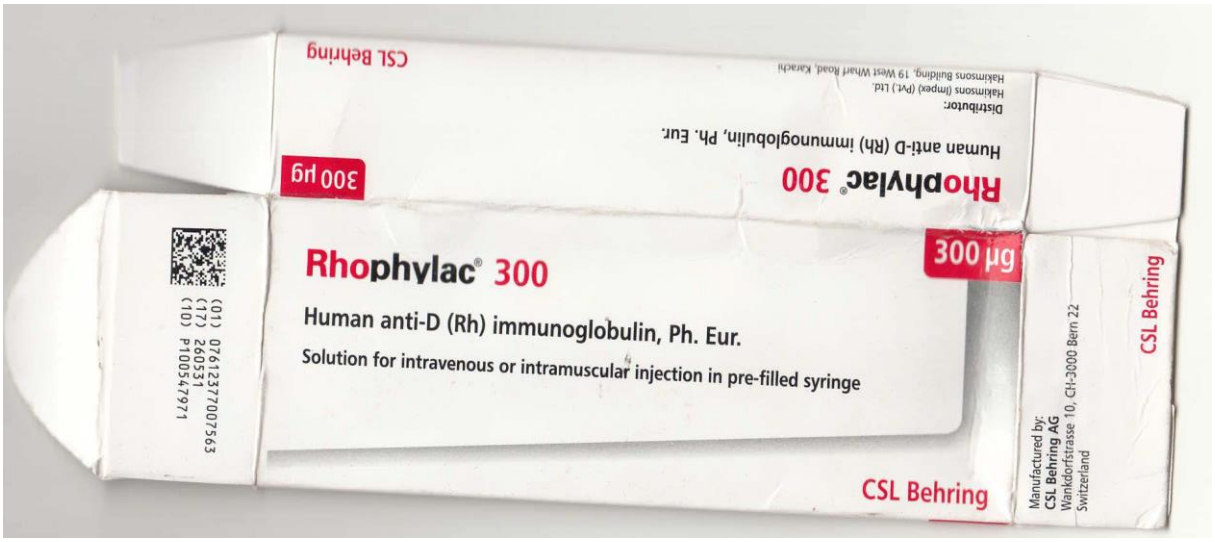
| Product name | Batches mentioned on pack | Stated Manufacturer (as per label) | Mfg. date | Exp. date |
|---|---|---|---|---|
| **Rhophylac 300mcg PFS**, Human Anti-D Immunoglobulin | P100547971<br>P100644011<br><br>Barcode Batch: P100585096 | M/s CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22, Switzerland. | 10-2023 | 09-2026 |

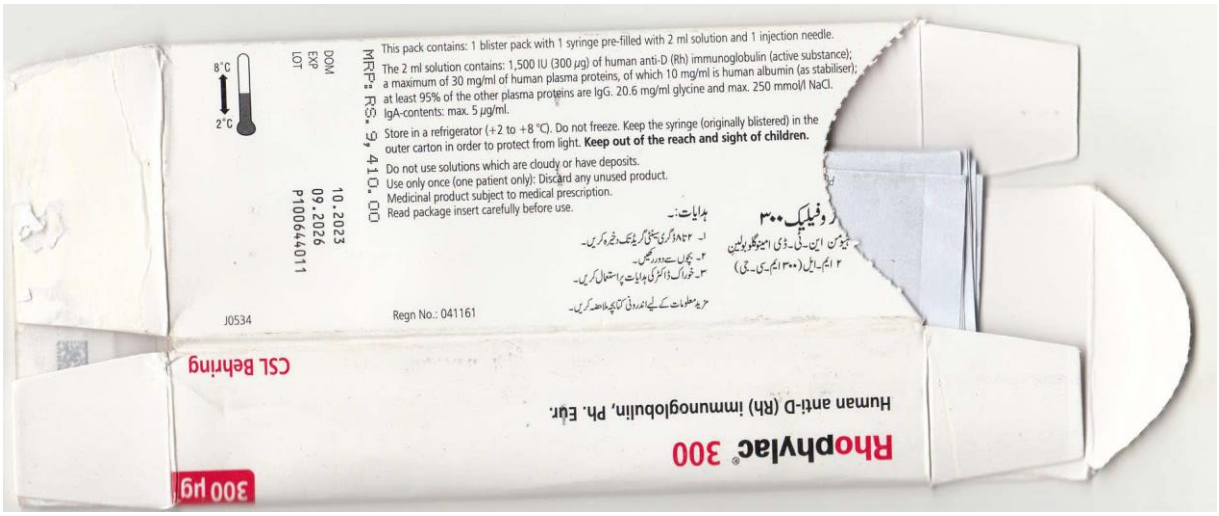
### Risk Statement:

The Anti-D immunoglobulin is a commercial biological antibody derived from human plasma that targets red blood cells (RBCs) positive for the Rh (D) antigen (also referred to as the D antigen). It is used to treat immune thrombocytopenic purpura (ITP) in patients with Rh-positive blood. Falsified Injectable products may cause severe and lethal adverse effects as the safety and quality attributes of the products are unknown.

**DRAP, Islamabad** **+ 92 051 9255969** **gsms@dra.gov.pk**

## Identification and details of falsified product:




**Lot Numbers :** P100547971, P100644011
**Barcode Batch**: P100585096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## Action Initiated: -

The Regulatory Field Force has been directed to increase surveillance throughout the supply chain to confiscate these products. All Pharmacists, chemists, and other healthcare professionals working at distributions, pharmacies, healthcare facilities, and other aspects of the supply chain system should immediately check the stock, and information related to the supplier of such products should be provided to the Regulatory field force (DRAP, Provincial Health Departments and States) to ensure the removal of this product.

## Advice for Healthcare Professionals: -

DRAP requests healthcare professionals to have increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by batches of above mentioned product. 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.

## Advice for Consumers:

Consumers should not use these products and should contact their physician or healthcare provider(s) if they have experienced any problem related to taking or using these products and should report the incident to the Drug Regulatory Authority of Pakistan / National Pharmacovigilance Centre.

All therapeutic goods must be obtained from licensed pharmacies and other authorized/licensed retail outlets. The authenticity and condition of products should be carefully checked. Seek advice from your pharmacists or other healthcare professionals in case of any doubt.

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

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