



RAPID ALERT

DRAP ALERT NO. N° I/S/08-23-30

UNREGISTERED AND FALSIFIED HYP-RHO-D INJECTION

(Distributed by M/s. Zaryab Traders, Lahore)

Date: 2nd August, 2023

Target Audience:

- Regulatory Field Force.
- Healthcare Professionals - Physicians, Pharmacists, and Nurses.
- General Public.

Problem Statement:

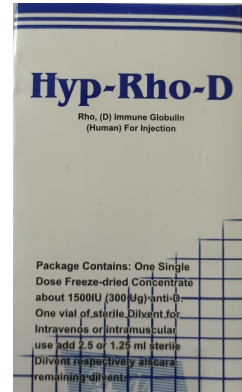
The Provincial Inspector of Drugs in Mansehra obtained a sample of the Hyp-Rho-D Injection from M/s. Abdullah Medical Store, located inside the Naseem Surgical Center, Upper Chennai Abbottabad Road, Mansehra. This particular product is not registered with the DRAP and is suspected to be falsified.

The product detail is as under: -

Product Name	Composition	Manufacturer / Distributor	Remarks
	(As stated on the label)		
Hyp-Rho-D Injection Registration No: Nil Batch No.: 09181943 Mfg. Date: - Exp. date: Aug 2024	Rho (D) immunoglobulin (Human) for injection	M/s. Woolmar Chemical Corporation, USA. Importer / Distributor: Ms. Zaryab Traders Lahore.	The product is not registered and is also suspected to be falsified.

Risk Statement:

The product claimed to contain immune globulin (anti-D immune globulin or RhIG), which 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. The claimed product is unregistered which infers that the quality and safety attributes of the product are not accepted and approved by DRAP. Unregistered injectable products may cause severe and lethal adverse effects as the safety and quality attributes of the product are unknown.



DRAP, Islamabad

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Action Initiated: -

The Regulatory Field Force has been directed to increase surveillance throughout the supply chain system including healthcare facilities to confiscate/seize this product from the market without any delay. 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 to halt the distribution/supply of this product. Information related to the supplier of this product 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 increased vigilance at hospitals and within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by this product.

Adverse reactions or quality problems experienced with the use of this product shall be reported to the National Pharmacovigilance Centre(NPC), DRAP 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 / General public: -

Consumers should not use this product and shall contact their physician or healthcare provider if they have experienced any problem related to taking or using this drug product, 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، مؤثر اور معیاری اشیائے علاج



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