



RAPID ALERT

DRAP ALERT NO. N° I/S/09-23-35

FALSIFIED ANTI-D IMMUNOGLOBULIN (HYP-RHO-D AND RHOCOLONE INJECTION)

Date: 22nd September, 2023

Target Audience:

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

Problem Statement:

It has been reported to DRAP that multiple spurious brands of Anti-D immunoglobulin, having no trace of legal import in Pakistan are being circulated in the market. Anti-D immunoglobulin is administered during pregnancy in case if a mother is RhD negative. Anti-D immunoglobulin can help to avoid a process known as sensitization, which is when a woman with RhD negative blood is exposed to RhD positive blood of fetus and develops an immune response to it. This condition can have severe consequences and may be life threatening to the new born.

The brands identified in Pakistan are Hyp-Rho-D purported to be manufactured by M/s. Woolmar Chemical Corporation USA and distributed by M/s. Zaryab Traders Lahore and Rhocolone® 300 mcg purported to be manufactured by M/s. Bharat Serums and Vaccines limited, India.

The manufacturer and stated distributor of Hyp-Rho-D injection are unknown and the authorized distributor of M/s. Bharat Serums and Vaccines limited India i.e. M/s. Hakimsons (impex) (Private) Ltd., Karachi have informed that their principal has not supplied any batch of product Rhocolne 300mcg to Pakistan.



DRAP, Islamabad

+ 92 51 910 73 17

gsms@dra.gov.pk

Identification and details of falsified product:

<p>Product Name: Hyp-Rho-D injection</p> <p>Lot. No.: 09181973</p> <p>Exp. Date: Jan 2025</p> <p>Mfg by: Woolmar Chemical USA</p> <p>Dst. By: Zaryab Traders Lahore</p>	 <p>The image shows the packaging for Hyp-Rho-D injection. On the left is a box with the product name and details: 'Hyp-Rho-D Rho, (D) Immune Globulin (Human) For Injection'. Below it, it states 'Package Contains: One Single Dose Freeze-dried Concentrate about 1500IU (300µg) Anti-D. One vial of sterile Diluent for Intravenous or Intramuscular use (add 2.5 or 1.25 ml Sterile Diluent respectively and care remaining diluent)'. To the right are two labels. The top one shows 'Lot 09181973' and 'Exp. JAN 2025', with an 'Important Store at 2-8-C'. The bottom one is in Urdu, stating 'تیل کئی ہو تو ہرگز استعمال نہ کریں' (Do not use if the seal is broken), '2 سے 18 ڈگری سینٹی گریڈ تک برقرار رکھیں' (Store between 2 to 18 degrees Celsius), 'Exp. JAN. 2025', 'MRP Rs. 9300', and 'زریاب ٹریڈرز لاہور، پاکستان' (Zaryab Traders Lahore, Pakistan).</p>
<p>Product Name: Rhocolne 300mcg</p> <p>Batch No.: 39VAN0065</p> <p>Mfg. Date: 05.11.2022</p> <p>Exp. Date: 05.10.2025</p> <p>Mfg by: Bharat Serums & Vaccines Limited, India.</p>	 <p>The image shows the packaging for Anti Rho-D Immunoglobulin Injection (Monoclonal). On the left is a box with the product name 'Anti Rho-D Immunoglobulin Injection (Monoclonal) RHOCLONE® 300 mcg (Freeze Dried) For Intramuscular Injection Only'. It also mentions 'Manufactured in India by: BHARAT SERUMS AND VACCINES LIMITED, Plot No. K-27 Additional M.I.D.C., Arambagh (S), - 421 301'. To the right is a label for 'AntiD' with a QR code and 'BSVwithU'. Below these are two more labels. The top one shows 'Mfg. Lot No. 21', 'Batch No. 39VAN0065', 'Date of Mfg. 05.11.2022', 'Date of Exp. 05.10.2025', and 'M.R.P. PKR - 10950'. The bottom one shows 'Sterile Water Mfg. Lot. No. 00341', 'Batch No. 00341', 'Date of Mfg. 16.01.2022', and 'Date of Exp. 16.12.2026'.</p>

Threats to Public Health: -

The use of falsified Anti-D immunoglobulin will result in the ineffective treatment of patients and will cause serious consequences for the new born effected from this conditions that may prove to be fatal. Moreover, the safety, sterility, and quality of the falsified products referenced in this alert are also unknown.





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، مونثر اور معيارى اشيائے علاج



DRAP, Islamabad

+ 92 51 910 73 17

gsms@dra.gov.pk