PRODUCT RECALL ALERT

DRAP ALERT NO. Nº I/S/05-24-20

RECALL OF NOVARISE 50mg/5mL SYRUP (BATCH NO. 113)

(MANUFACTURED BY M/S. SHAROOQ PHARMACEUTICALS (PVT.) LTD., LAHORE)

Date: 15th May 2024.

Target Audience:

- National Regulatory Field Force.
- Pharmacists and Chemists at Distribution, Pharmacies and Medical Stores
- Healthcare Professionals- Physicians, Pharmacists, and Nurses at hospital and clinics etc.

Alert Summary:

Federal Government Analyst, CDL Karachi vide test report No. LHR-1-24-000001 dated 03-04-2024 has declared the Novarise Syrup Batch No. 113 as of **substandard quality** on the basis of presence of Ethylene Glycol impurity at unacceptable level.

Details of the affected product is as under:

Product Name	Composition	Batch Details	Manufactured by	Remarks
Novarise 50mg/5mL Syrup	Iron (iii) Hydroxide Polymaltose complex	**Batch No. 113**	M/s Sharooq Pharmaceuticals (Pvt.) Ltd., Lahore	The analysis revealed 0.7818% ethylene glycol, which does not comply.

Risk Assessment: -

The presence of Ethylene Glycol (EG) in oral liquid preparations poses serious health risks due to its toxicity as small amounts of EG can be fatal, especially for children. When ingested, both diethylene glycol (DEG) and EG are metabolized into toxic compounds that can adversely affect the central nervous system, heart, and kidneys**.**

Action Initiated: -

The manufacturer has been directed to immediately recall the defected batch of product from the market. All pharmacists and chemist working at distributions and pharmacies should **immediately check** their stocks and stop supplying this batch of product. The remaining stock 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).

DRAP, Islamabad | 92 51 9107404 | gsms@dra.gov.pk

-Distributors and pharmacies are advised to be vigilant and report any suspected batch of the product(s) in the supply chain to the DRAP using the **online form**, or through whatsApp at +92 51 910 73 17, or by Email at gsms@dra.gov.pk.

Advice for Healthcare Professionals: -

DRAP requests increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by this affected batch of products.

Adverse reactions or quality problems experienced with the use of this product may be reported to the National Pharmacovigilance Centre (NPC), DRAP using the 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 stop using this product bearing the affected batch number(s) and shall contact to their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product, and report the incident to the Drug Regulatory Authority of Pakistan/ National Pharmacovigilance Centre.

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

Drug Regulatory Authority of Pakistan
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