RECALL ALERT

DRAP ALERT NO. N^{o} I/S/09-24-34

RECALL OF PROMASS 1GM/100ML INF (BATCH #034)

(MANUFACTURED BY M/S TREAT PHARMACEUTICAL INDUSTRY PVT. LTD., BANNU)

Date: 23rd September, 2024.

Target Audience:

- National Regulatory Field Force of DRAP and Provincial Drug Control Departments.
- Healthcare Professionals (Physicians, Pharmacists & Nurses, etc.)
- General Public.

Alert Summary:

The Provincial Drug Inspector, Dera Ismail Khan, KPK has informed DRAP that samples of following product has been declared substandard by the provincial Drug Testing Laboratory, KPK, Peshawar. Details of test report are as under:

Product Name	Composition	Batch	Mfg. Date	Exp. Date	Manufacturer	Test Results
Promass 1gm/100ml Inf Reg.No. 075336	Paracetamol	**034**	01-07-2023	30-06-2025	M/s. Treat Pharmaceutical Industry (Pvt.) Ltd, Kohat Road, Bannu	Substandard

Risk Statement:

Identification of visible particles in infusion products is a serious indicator of substandard quality, which can lead to significant health risks including severe reactions such as shivering, high fever, arterial blockages, infarction and more serious adverse events.

Action initiated: -

The manufacturer has been directed to immediately recall the defective batch of product from the market. The regulatory field force of all federating units (DRAP and Provincial Health Departments) has increased surveillance in the market to ensure the effective recall of defective products.

Advice for Pharmacies/Medical stores: -

All pharmacists and chemist working at distributions and pharmacies should **immediately check** their stocks and stop supplying mentioned product. The remaining stocks should be quarantined and returned to the supplier/company.

-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 by sending an 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 batches of mentioned products. Adverse reactions or quality problems experienced with the use of these products are to 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: -

Consumers should stop using products 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 Drug Regulatory Authority of Pakistan/ National Pharmacovigilance Centre.

Drug Regulatory Authority of Pakistan
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