DRUG REGULATORY AUTHORITY OF PAKISTAN
DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/09-25-65

Lipidem® / Lipoplus® Emulsion for Infusion (Zone IV Stability Risk for Pakistan)

Date: 17th September, 2025

Target Audience:

- **Hospitals (Public & Private)**: especially those with ICU, surgical, oncology, and nutrition support units.
- **Parenteral Nutrition Centre / Clinical Nutrition Teams:** where lipid emulsions are routinely administered.
- **Pharmacists**: particularly hospital pharmacists and those in charge of sterile/IV admixtures.
- **Physicians:** especially intensivists, anesthesiologists, gastroenterologists, and pediatricians using parenteral nutrition.
- **Provincial Health Authorities & Regulatory Bodies:** to ensure monitoring and enforcement at the provincial level.
- **Importer & Distributors:** of Lipidem® / Lipoplus® in Pakistan.
- **Nursing Staff:** involved in IV infusion preparation and administration.

Problem Statement:

Stability studies conducted by the manufacturer and German regulatory authority identified **droplet-like agglomerates (subvisual fat particles)** in Lipidem® / Lipoplus® emulsions stored at **25°C beyond 12 months**. These agglomerates, if infused without appropriate filtration, may lead to **serious adverse events, including fat embolism in pulmonary capillaries**. The details of the product is as under: -

S#	Reg. #	Name of Drug(s) & Composition	Packing	Shelf Life	Importer details
1.	099492	**Lipoplus Emulsion for Intravenous Infusion** Each 1000 ml contains: Medium chain triglycerides…. 100gm Soya oil …… 80gm Omega-3-acid triglycerides... ....20gm (As per Innovator's Specification)*	250m1 Glass Bottle	02 years	M/s B.Braun Pakistan (Pvt) Ltd, The Forum, Suite 216 Khayaban-e-Jami, Clifton Block 9, Karachi. **Godown address:** Ground Floor Plot No. C-153, S-6F, Mehran Town, Karachi

Risk Statement:

In stability studies conducted in Germany, droplet-like agglomerates were detected **in Lipidem® / Lipoplus® emulsions stored at** 25 °C beyond 12 months**.** To mitigate this risk under those conditions, the German authority recommended the use of a 1.2 µm lipid infusion filter during administration.

Since Pakistan falls under Zone IV climatic conditions (hot and humid)**, which differ significantly from Germany (25°C),** the risk of earlier onset of agglomerate formation cannot be excluded**.** To date, no stability information or scientific justification for Zone IV conditions has been provided by the manufacturer or Marketing Authorization Holder (MAH)**.** Considering these factors and the higher temperature and humidity in Pakistan**,** the matter is classified as a **Class I recall risk,** as the defect may reasonably be expected to cause **serious adverse health consequences if not managed appropriately.**

Action initiated: -

The field force of DRAP and Provincial Drug Control departments have been directed to immediately conduct market surveys for detection of presence and removal of mentioned batches from the market.

Advice for Pharmacies/Medical stores: -

All pharmacists and chemist working at distributions and pharmacies should **immediately check** their stocks and stop supplying mentioned products. The remaining stocks 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).

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 above mentioned product 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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