RAPID ALERT

DRAP ALERT NO. Nº I/S/09-24-37

FALSIFIED LIPIODOL ULTRA FLUIDE 480MG/ML INJECTION

Date: 05th October, 2023

Target Audience:

- Regulatory Field Force.
- Healthcare Professionals - Physicians, Pharmacists, and Nurses.
- Procurement officer at hospitals and institutions
- General Public.

Problem Statement:

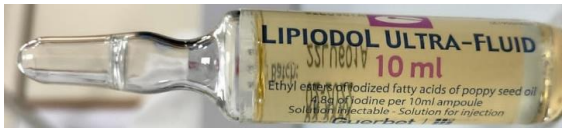
The regulatory field force of DRAP and the Chief Drug Inspector Office, Karachi have identified a suspected falsified lot of Lipiodol Ultra Fluide 480mg/ml Injection which was intended to supply to tertiary care hospitals. The said product is not registered in Pakistan and is not imported using special permission pathways.

Details of falsified product are given as under:

Product Name	**Composition**	**Batch / Lot**	**Manufactured as stated on label:**	**Remarks**
Lipiodol Ultra Fluide 480mg/ml Solution for Injection (10ml) **Registration No.:** Nil	Ethiodized-oil (radio-opaque contrast injection)	Batch No.: **15LU606A** Exp. Date: **07-2024**	Guerbet, 15 rue des Vanesses, Zone Paris Nord II France	The outer packaging, solution colour and consistency were different from the comparison to the original product.

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

Identification of Original / Falsified Product:

Original Product	Falsified Product
 	 

Threats to Public Health: -

The use of falsified or counterfeit Lipiodol injection can pose serious health risks as it may contain unknown ingredients or no active ingredient at all. This can lead to ineffective treatment, worsening of the condition, or unexpected side effects. In some cases, falsified products have been found to contain toxic materials which expose patients to harmful substances. 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. Since this product is not registered with DRAP, it is not permitted to be stocked or sold in pharmacies or other retail outlets. However, it is crucial for all healthcare professionals, including pharmacists and chemists, to check their stock immediately and stop the distribution or supply of this product if it is found. 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.

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

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 should 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، موثر اور معیاری اشیائے علاج

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