PRODUCT RECALL ALERT

DRAP ALERT NO. Nº I/S/12-23-47

RECALL OF CETAFEND Infusion (Batch #23RC55)

(MANUFACTURED BY M/s. FRIENDS PHARMA (PVT.) LTD. LAHORE)

Date: 28th December, 2023

Target Audience:

- Pharmacists and Chemists at Distribution, Pharmacies and Medical Stores
- Healthcare Professionals- Physicians, Pharmacists, and Nurses at hospital and clinics etc.
- General Public

Alert Summary:

Federal Government Analyst, CDL Karachi vide test report No. KQ-11-23-000155 dated 12-12-2023 has declared the Cetafend Infusion Batch No. 23RC55 as of substandard quality.

Details of the affected product is as under:

Product Name	Composition	Batch Details	Manufactured by	Remarks
Cetafend 1g/100mL Infusion Reg.No 091872	Paracetamol	**Batch No. 23RC55** Mfg. Date: 10-2023 Exp. date: 10-2025	M/s Friends Pharma (Pvt.) Ltd., 31-Km Ferozepur Road, Lahore	Containing particles visible to naked eye.

Risk Assessment: -

Cetafend Infusion contains Paracetamol, a medicine used to treat mild to moderate pain. Paracetamol can also be used to treat fever (high temperature). Administration of products containing visible solid particles to patients through IV infusion may lead to complications, as well as an increased risk of venous thromboembolism. The age-profile of patients is important and young patients especially seem to be at risk.

Action Initiated: -

The manufacturing company has been directed to immediately recall the defective batch of the above-mentioned product from the market. All pharmacists and chemists working at distributions and pharmacies are hereby advised to **immediately check** their stocks and stop supplying this batch of product. The remaining stock should be quarantined and returned to the supplier/ company.

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

The regulatory field force of DRAP and Provincial Health Departments has increased surveillance in the market to ensure the effective recall of defective products(s).

-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 phone 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 product. 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 of 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 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.

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Drug Regulatory Authority of Pakistan
محفوظ، موثر اور معیاری اشیائے علاج

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