PRODUCT RECALL ALERT

DRAP ALERT NO. Nº I/S/05-24-23

VOLUNTARY RECALL OF CADLEC INJECTION 30MG/ML- ALL BATCHES

(MANUFACTURED BY MS. BROOKES PHARMA PRIVATE LIMITED, KARACHI)

Date: 24th 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:

M/s. Brookes Pharma Private Limited, Karachi, has initiated a voluntary recall of all batches of Cadlec 30mg/ml Injection due to the presence of tiny floating particles found in retained samples. Previously, Ketorolac injection was also recalled by Fresenius Kabi, USA, and Hospira Inc. Additionally, Hikma Pharmaceutical, USA, also recalled the injection for the same reason.

Details of the affected product is as under:

Product Name	Composition	Batch Details	Manufactured by
Cadlec Injection 30mg/ml Reg No. 095892	Ketorolac	**All Batches**	M/s. Brookes Pharma Private Limited, Karachi

Risk Assessment: -

Administering products containing particulate matter may block blood vessels, leading to local irritation, swelling, tissue inflammation, blood clots, lung tissue scarring, and life-threatening allergic reactions.

Action Initiated: -

The manufacturer has initiated recall of all batches of the affected product from the market. All pharmacists and chemist working at distributions and pharmacies should **immediately check** their stocks and stop supplying this 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) has 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 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 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 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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