RAPID ALERT

DRAP ALERT NO. Nº I/S/05-24-22

FALSIFIED FROXIME 100MG/5ML POWDER FOR ORAL SUSPENSION

Date: 27th May 2024

Target Audience:

- Regulatory Field Force.
- Healthcare Professionals - Physicians, Pharmacists, and Nurses.
- Procurement Managers at Hospitals, Clinics, Pharmacies and other Healthcare Institutions
- General Public.

Problem Statement:

The Provincial Inspector of Drug Tehsil Kallurkot, Dist. Bhakkar inspected the premises of Ms. Dar ul Shifa Pharmacy near THQ Hospital Tehsil Kallur Kot district Bhakkar and collected samples of Froxime Suspension (Batch no FRX-100/S-005; manufactured by Ms. Froxx Pharmaceuticals Plot No 87 KIA Karachi). The Government analyst DTL Rawalpindi has declared the Froxime Suspension as Substandard and Spurious.

The details of the product is as under:-.

Product Name	Composition	Batch details (as per label)	Manufactured by	Remarks
Froxime 100mg/5mL Powder for oral Suspension Reg No. 555210 (Fake number)	Cefixime USP	Batch No. FRX-100/S-005 Mfg. Date: 03-23 Exp. Date: 02-25	Ms. Froxx Pharmaceuticals Plot No 87 Korangi Industrial Area, Karachi. (Fake company)	The sample is declared as spurious under section 3(z-b) (i) of the Drugs Act, 1976.

Note: *There is no product registered in DRAP with the name "Froxime Powder for Oral Suspension", and there is no licensed manufacturing company named as "Froxx Pharmaceutical Karachi".*

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

Risk Statement:

Spurious or falsified pharmaceuticals may contain harmful levels of toxic substances, posing a significant risk of widespread poisoning. These substandard medications have the potential to undermine the efficacy of disease treatment and exacerbate preexisting medical conditions.

Action Initiated: -

The Regulatory Field Force has been instructed to increase surveillance activities at health facilities (hospitals), as well as markets, and confiscate any such falsified products. All pharmacists and chemists working at distributions and pharmacies should immediately check their stock and stop supplying any suspected products.. The remaining stock should be quarantined immediately, and supplier information should be provided to the Regulatory Field Force (DRAP, Provincial and State Drug Control Administrations) to ensure the removal of these products.

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 of reporting problems to DRAP is available on this link.

Advice for Consumers / General Public: -

Consumers should stop using this product and shall contact 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 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، موئثر اور معیاری اشیائے علاج

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