

PRODUCT RECALL ALERT

DRAP ALERT NO. Nº I/S/11-22-38

RECALL OF XIMEX 100MG/5ML SUSPENSION

(Manufactured By Farmaceutics International Karachi, Pakistan)

Date: 30th November, 2022

Target Audience:

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

Problem Statement:

Federal Government Analyst, CDL Karachi has declared the Batch No. F-C-539 of product 'Ximex 100mg/5mL Suspension" as of substandard quality based on the analysis report. Detail of the product is as under: -

Product Details	Composition	Manufactured by	Remarks
Ximex 100m/5mL Suspension	Cefixime	M/s. Farmaceutics	The sample is of Sub-
(Reg.No 042408)	100mg/5mL	International	standard quality on basis
Batch No. F-C-539		Karachi	of non-conforming
Mfg. Date: 06-2022 Exp. date: 06-2024			Assay, results.

Action Initiated: -

The manufacturing company has been directed to immediately recall the defected batch of product from the market. All Pharmacists and chemists working at distributions and Pharmacies should **immediately check** their stocks and **stop supplying** this batch of product. The remaining stock should be quarantine and return to the supplier / company. Regulatory field force of all federating units (DRAP, Provincial Health Departments and States) have also increased surveillance in the market to ensure the effective recall of this defective product.

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 Adverse Event Reporting Form or online through this <u>link</u>. Further information of reporting problems to DRAP is available on this <u>link</u>.

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.





