PRODUCT RECALL ALERT

DRAP ALERT NO. Nº I/S/10-22-25

RECALL OF FENTOS TABLETS

(MANUFACTURED BY M/S HISUN PHARMACEUTICAL INDUSTRIES, GADOON-PAKISTAN)

Date: 06th October 2022

Target Audience:

- Healthcare Professionals- Physicians, Pharmacists, and Nurses.
- General Public.

Problem Statement:

The sample of Fentos Tablets was taken by FID for test/ analysis and sent to CDL, Karachi. Federal Government Analyst declared the batch No. 599 of "Fentos Tablets" as "Substandard". Details of the product are:

Product Name	Batch No.	Mfg. date	Exp. date	Manufactured by	Test/Analysis result of CDL
Fentos tablets	599	09-21	09-23	M/s. Hisun Pharmaceutical Industries, Gadoon-Pakistan.	**Dissolution:** Does not comply.

Action Initiated: -

The company is directed to immediately recall the defected batch of product(s) from the market. All Pharmacists and chemists working at distributions and Pharmacies are required to **immediately return** the stock of above mentioned batch of product to the 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 defective product(s).

Advice for Healthcare Professionals: -

DRAP requests increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by this substandard batch.

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 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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