PRODUCT RECALL ALERT

DRAP ALERT NO. Nº I/S/10-22-32

RECALL OF MOXTREX 400MG TABLETS (Batch # 850)

(Manufactured by M/s. Gillman Pharmaceuticals, Hattar)

Date: 03rd 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:

DTL Rawalpindi has declared the batch No. 850 of product "Moxtrex 400mg Tablets" manufactured by M/s. Gillman Pharmaceuticals, Hattar, as "**substandard**" drug product. Details of the product are given as under:

Product Name	Composition	Batch No.	Mfg. date	Exp. date	Manufactured by	Remarks
Moxtrex 400mg Tablets **(Reg. 078485)**	Moxifloxacin	850	06-2022	06-2024	M/s. Gillman Pharmaceuticals, Hattar	Substandard on physical characteristics

Action Initiated: -

The company is 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 batches 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 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.

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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 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 only 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.