PRODUCT RECALL ALERT

DRAP ALERT NO. Nº II/S/09-23-34

RECALL OF ALBEX 200MG TABLET (BATCH # 112)

(MANUFACTURED BY M/S. SWAT PHARMACEUTICAL, SWAT)

Date: 22nd Sep, 2023

Target Audience:

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

Alert Summary:

Federal Government Analyst, CDL Karachi has declared the Batch No. 112 of product "Albex Tablet" as of **substandard** quality.

The detail of the product is as under:

Product Name	**Composition**	**Batch Detail**	**Manufactured by**	**Remarks**
Albex 200mg Tablet Reg No. 020921	Albendazole	**Batch No. 112** Mfg. Date: 04-2023 Exp. Date: 03-2025	Ms. Swat Pharmaceutical, Swat.	The sample does not meet the acceptance criteria for dissolution test and is considered of sub-standard quality.

Risk Statement:

Albendazole is an anthelminthic drug used to treat various parasitic worm infections. Substandard preparations of albendazole tablets may lead to treatment failure or suboptimal therapeutic effects, adverse effects, and increased antimicrobial resistance by exposing the parasitic worms to suboptimal concentrations of the drug.

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Action Initiated: -

The manufacturer has been directed to immediately recall the defective 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 quarantined and returned to the supplier/ company. The regulatory field force of all federating units (DRAP and Provincial Health Departments) has also increased surveillance in the market to ensure the effective recall of defective products(s).

Advice for Healthcare Professionals: -

DRAP requests to enhance **vigilance** within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by the defective lot/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 the 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 the National Pharmacovigilance Centre of Drug Regulatory Authority of Pakistan, through MedSafety Mobile Application, or online at Med Vigilance E Reporting System.

All therapeutic goods must be obtained from 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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