PRODUCT RECALL ALERT

DRAP ALERT NO. Nº I/S/11-23-44

RECALL OF ESPEZAR 20mg Tablets (Batch #A401)

(MANUFACTURED BY M/S AVANT PHARMACEUTICAL PVT. LTD, HUB, BALUCHISTAN)

Date: 21st December, 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 informed DRAP regarding the sample of product namely "Espezar tablet" Batch No. A401 manufactured by M/s. Avant Pharmaceuticals (Pvt.) Ltd., Plot No. 28 Hub Industrial Estate, Hub Balochistan has been declared as of "Substandard" quality. Details of the affected product is as under:

Product Name	Composition	Batch Details	Manufactured by:	Remarks of CDL
Espezar 20mg Tablets Reg.No 102983	Esomeprazole	Batch No. **A401** Mfg. Date: 11-22 Exp. date: 11-24	M/s Avant Pharmaceutical Pvt. Ltd, Hub, Baluchistan	The Dissolution (Acid stage) and the Assay test (84.96%) fail to comply with the specifications

Risk Statement:

Esomeprazole is used to treat certain stomach and esophagus problems (such as acid reflux, ulcers). It works by decreasing the amount of acid the stomach makes. It relieves symptoms such as heartburn, difficulty swallowing, and cough. This medication helps heal acid damage to the stomach and esophagus, helps prevent ulcers, and may help prevent cancer of the esophagus. Esomeprazole belongs to a class of drugs known as proton pump inhibitors (PPIs). Impact of use of substandard product may leads to sub optimal therapeutic effect which may cause therapy failure or other associated problems.

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

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).

-Distributors and pharmacies are advised to be vigilant and report any suspected batch of the product(s) in the supply chain to the DRAP using the **online form**, or through phone at +92 51 910 73 17, or by Email at gsms@dra.gov.pk.

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 should 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, through MedSafety Mobile Application, or online at Med Vigilance E Reporting System.

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.

Drug Regulatory Authority of Pakistan
محفوظ، موثر اور معیاری اشیائے علاج

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