PRODUCT RECALL ALERT

DRAP ALERT NO. Nº II/S/10-23-41

RECALL ALERT OF PIPERAZINE ELIXIR (Batch # L-085)

(MANUFACTURED BY SWAT PHARMACEUTICALS, SAWAT)

Date: 20th November, 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. L085 of product "Piperazine Elixir" as of **substandard** quality

The detail of the affected product is as under:

Product Name	Composition	Batch	Manufactured by:	Remarks of CDL
Piperazine 750mg/5ml Elixir Reg.No 002235	Piperazine Citrate	Batch No. L-085 Mfg. Date: 06-23 Exp. date: 05-25	Ms. Swat Pharmaceuticals, Saidu Sharif Swat.	The sample is of Sub-standard quality (on basis of pH and assay test which does not comply with acceptance criteria).

Risk Statement:

Piperazine Citrate is used to treat common roundworms (ascariasis) and pinworms (enterobiasis; oxyuriasis). To avoid the common side effects of gastrointestinal disturbances, headache, dizziness, and urticaria, it is important to use the product accurately.

It is critical to ensure that the product is not substandard, as its use can significantly alter the dose and lead to suboptimal therapeutic effects.

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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 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، موئثر اور معیاری اشیائے علاج

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