RAPID ALERT

DRAP ALERT NO. Nº I/S/02-24-07

SPURIOUS DUPHASTON TABLET BATCH NO. 223298 AND FEMARA TABLET BATCH NO. TTT60

Date: 16th February, 2024.

Target Audience:

- Regulatory Field Force
- Healthcare Professionals- Surgeons, Pharmacists, and Nurses
- Pharmacists and Chemists at Distribution, Institutional suppliers
- General Public

Problem Statement:

The Regulatory Field Force of Punajb has identified suspected samples in the market and sent them to the Drug Testing Laboratories for testing / analysis. The Government Analysts reported that three of these products have been identified as falsified or spurious. Upon investigation, the manufacturing companies mentioned on the labels of these products have confirmed that they these products were not manufactured nor supplied by themselves.

Identification and details of Falsified product:

S#	Product Name and composition	Composition	Batch No.	Manufacturer Name as per label	Remarks/Results
01	**Duphaston 10mg Tablet**	Dydrogesterone 10mg	223298	M/s. Highnoon Laboratories Ltd, 17-Km Multan Road, Lahore.	Spurious (contain no active ingredient)
02	**Femara 2.5mg Tablet**	Letrozole 2.5mg	TTT60	M/s. Novartis Pharma Stein AG SCHAFFHAUSERSTRASSE	Spurious (contain no active ingredient)
03	**Oxidil 1g Inj**	Ceftriaxone	050K	M/s Healthtek Pvt. Ltd, Karachi	Substandard for non-complying assay and sterility test. Also Declared as spurious

DRAP, Islamabad **+ 92 51 910 73 17** **gsms@dra.gov.pk**

Threats to Public Health: -

The use of these falsified products will result in the ineffective treatment of patients. Moreover, the safety and quality of the falsified products referenced in this alert are also unknown.

Action Initiated: -

The Regulatory Field Force has been directed to increase surveillance throughout the supply chain system including healthcare facilities to confiscate/seize this product from the market without any delay. All Pharmacists, chemists, and other healthcare professionals working at distributions, pharmacies, healthcare facilities, and other aspects of the supply chain system should immediately check the stock to halt the distribution/supply of this product. Information related to the supplier of this product should be provided to the Regulatory field force (DRAP, Provincial Health Departments, and States) to ensure the removal of this product.

Advice for Healthcare Professionals: -

DRAP requests increased vigilance at hospitals and within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by this product.

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 on reporting problems to DRAP is available on this link.

Advice for Consumers / General public: -

Consumers should not use this product and shall contact their physician or healthcare provider if they have experienced any problem related to taking or using this drug product, and should report the incident to the Drug Regulatory Authority of Pakistan / National Pharmacovigilance Centre.

All therapeutic goods must be obtained from licensed pharmacies and other authorized/licensed retail outlets. The authenticity and condition of products should be carefully checked. Seek advice from your pharmacists or other healthcare professionals in case of any doubt.

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

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