DRUG REGULATORY AUTHORITY OF PAKISTAN
DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº II/S/09-25-58

DRUG PRODUCTS DECLARED SUBSTANDARD BY CENTRAL DRUGS LABORATORY, KARACHI

Date: 10th September, 2025

Target Audience:

National Regulatory Field Force of DRAP and Provincial Drug Control Departments.

Healthcare Professionals (Physicians, Pharmacists & Nurses).

General Public.

Alert Summary:

Central Drugs Laboratory Karachi informed the Drug Regulatory Authority of Pakistan that the samples of below mentioned drug products have been declared as '***Substandard***'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**Famila 28F Tablets** Each Tablet contains: Levonorgestrel...0.15mg Ethinyl Estradiol...0.03mg Ferrous Iron….24.37mg (Reg. No. 023941)	K159	**M/s. ZAFA Pharmaceutical Laboratories (Pvt.) Ltd.** A-46 SITE North Karachi **(DML#000490)**	Central Drugs Laboratory declared the Famila 28F Tablets (Batch # K159) as **'Substandard'** on the basis of out of specification results for the test of content uniformity of Levonorgestrel & weight variation of Ferrous Iron.
2.	**Famila 28F Tablets** Each Tablet contains: Levonorgestrel...0.15mg Ethinyl Estradiol...0.03mg Ferrous Iron….24.37mg (Reg. No. 023941)	K198	**M/s. ZAFA Pharmaceutical Laboratories (Pvt.) Ltd.** A-46 SITE North Karachi **(DML#000490)**	Central Drugs Laboratory declared the Famila 28F Tablets (Batch # K198) as **'Substandard'** on the basis of out of specification results for the test of content uniformity of Levonorgestrel & Ethinyl Estradiol, weight variation of Ferrous Iron & Assay of Levonorgestrel & Ethinyl Estradiol.

3.	**Famila 28F Tablets** Each Tablet contains: Levonorgestrel...0.15mg Ethinyl Estradiol...0.03mg Ferrous Iron….24.37mg (Reg. No. 023941)	K196	**M/s. ZAFA Pharmaceutical Laboratories (Pvt.) Ltd.** A-46 SITE North Karachi **(DML#000490)**	Central Drugs Laboratory declared the Famila 28F Tablets (Batch # K196) as **'Substandard'** on the basis of out of specification results for the test of content uniformity of Levonorgestrel & Ethinyl Estradiol, weight variation of Ferrous Iron & Assay of Levonorgestrel.
4.	**Famila 28F Tablets** Each Tablet contains: Levonorgestrel...0.15mg Ethinyl Estradiol...0.03mg Ferrous Iron….24.37mg (Reg. No. 023941)	K197	**M/s. ZAFA Pharmaceutical Laboratories (Pvt.) Ltd.** A-46 SITE North Karachi **(DML#000490)**	Central Drugs Laboratory declared the Famila 28F Tablets (Batch # K197) as **'Substandard'** on the basis of out of specification results for the test of content uniformity of Levonorgestrel & Ethinyl Estradiol, weight variation of Ferrous Iron & Assay of Levonorgestrel & Ethinyl Estradiol.

Risk Statement:

***Famila 28F*:** The affected batches of *Famila 28F Tablets* due to content uniformity, assay failures of hormonal ingredients, and weight variation in the iron component, may lead to reduced contraceptive efficacy, hormonal imbalance, and inconsistent iron supplementation, increasing the risk of complications, particularly in vulnerable groups such as Young Women, Perimenopausal Women, Women with history of Anemia, Patients with Comorbidities.

Action initiated: -

The field force of DRAP and Provincial Drug Control departments have been directed to immediately conduct market surveys for detection of presence and removal of mentioned batches from the market.

Advice for Pharmacies/Medical stores: -

All pharmacists and chemist working at distributions and pharmacies should **immediately check** their stocks and stop supplying mentioned products. The remaining stocks should be quarantined and returned to

the supplier/company. Regulatory field force of all federating units (DRAP and Provincial Health Departments) should also increase 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 batches of mentioned products. Adverse reactions or quality problems experienced with the use of above mentioned product are to 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 products 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.

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