MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/11-24-47

SUBSTANDARD HI-Z SYRUP BATCH NO. S1427

(MANUFACTURED BY M/S. GULF PHARMACEUTICALS, PLOT. NO. 49, S-5 NIZ RAWAT ISLAMABAD)

Date: 08th November, 2024.

Target Audience:

- Physicians, Pharmacists, Nurses and General Public.

Alert Summary:

Federal Government Analyst, CDL Karachi has declared the following products as of substandard quality. Details of CDL test report are as under:

S.No	Product	Mfg. by	Batch No.	Mfg. / Exp.	CDL Test Result
01	Hi-Z syrup (20mg Elemental Zinc/5ml) (Reg. no. 075129)	M/s. Gulf Pharmaceuticals, Islamabad	S1427	Mfg: 07-24 Exp: 06-26	Substandard on the basis of assay.
02	Ufen Oral Suspension (100mg Ibuprofen/5ml) (Reg. No. 090274)	M/s. Gulf Pharmaceuticals, Islamabad	S1451	Mfg: 08-24 Exp: 07-26	Substandard on the basis of pH

Risk Statement:

Elemental Zinc syrups are used for reduction of duration and severity of diarrhea in children who are undernourished. Moreover, in patients suffering from Wilson disease, taking zinc by mouth improves symptoms by blocking how much copper is absorbed and increases how much copper the body releases. Sub-standard Zinc preparations may lead to complications in above mentioned conditions.

Ibuprofen is a nonsteroidal anti-inflammatory drug (NSAID) commonly used to reduce fever, pain, and inflammation. Altered pH of an oral preparation may lead to gastrointestinal irritability, decreased stability and altered absorption of the product. These factors can ultimately lead to the therapy failure.

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Action initiated: -

The manufacturer has been directed to immediately recall the defected batches of mentioned products from the market. All pharmacists and chemist working at distributions and pharmacies are hereby advised to **immediately check** their stocks and stop supplying this batch of product. The remaining stock should be quarantined and returned to the supplier/ company. Regulatory field force of DRAP and Provincial Health Departments are also informed regarding the matter and are directed to 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 this affected 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 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.

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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