RAPID ALERT

DRAP ALERT NO. Nº I/S/06-23-27

FALSIFIED/UNREGISTERED N-GAISK PLUS TABLETS

(MANUFACTURED BY NAZ HOMOEO PHARMACY, KARACHI)

Date: 19h June 2023

Target Audience:

- Pharmacists and Chemists at Distribution, Pharmacies, and Medical Stores
- Healthcare Professionals- Physicians, Pharmacists, and Nurses at hospitals and clinics etc.
- General Public

Problem Statement:

Federal Inspector of Drugs Karachi took the sample of N-Gaisk Plus Tablets and sent it to Central Drug Laboratory, Karachi for testing/analysis. Federal Government Analyst has declared the sample as Unregistered under the Drugs Act 1976. Details of the product are:-

Product Name	**Manufactured by**	**Remarks by Laboratory**
N-Gaisk Plus Tablets **Registration No. Nil** Batch No. **004** Mfg. Date: Aug 2022 Exp. date: Aug 2028	M/s. Naz Homoeo Pharmacy, Karachi	Diclofenac sodium has been identified on the assay test (24.81mg) which is an allopathic drug, and the sample is not registered with DRAP. Hence the sample is declared as "Un-registered Drug Product"

Risk Statement:

The Claimed Product is Homoeopathic with some quantity of an allopathic ingredient Diclofenac Sodium which is an Anti-Inflammatory/Rheumatic drug used to treat Rheumatoid Arthritis and associated pains. As the product is unregistered this infers that the quality and safety attributes of the product are not accepted and approved by DRAP.

Unregistered products containing Diclofenac Sodium may cause severe adverse reactions including Gastric bleeding and diarrhea.

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

Action Initiated: -

The Regulatory Field Force has been directed to increase the surveillance activities at Health facilities (Hospitals) in addition to markets and confiscate the batch of products if available. All Pharmacists and chemists working at distributions and Pharmacies should **immediately check** the stock and stop supplying this batch product. The remaining stock should be quarantined immediately, and supplier(s) information should be provided to the Regulatory field force (DRAP, Provincial Health Departments, and States) in order to ensure the removal of these products.

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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