



RAPID ALERT

DRAP ALERT No: I/S/12-24-56

FALSIFIED PRODUCT ASKINOREN GEL (AZELAIC ACID 15%) PURPORTEDLY MANUFACTURED BY M/S. MEDSHARE PHARMA RISALPUR, KPK

Date: 10th December, 2024

Target Audience:

- Regulatory Field Force of DRAP and Provincial Drug Control departments.
- Healthcare Professionals
- Pharmacies and medical stores

Problem Statement:

The firm M/s OBS Pharma (Pvt.) Limited, Karachi, has notified DRAP regarding the presence of falsified product “Askinoren Gel” in the market across Pakistan. The primary packaging of the product shows no Batch number and Expiry date. Also, a different brand name **Acnoren** was mentioned under the heading of dosage. Moreover, there was no Urdu instruction and dosage required as per Labelling Rules, 1986. The details of the identified product are as under:

Product name	Batch/Lot No.	Stated Manufacturer	Mfg. date	Exp. date
Askinoren Gel (Azelaic Acid 15%)	Nil	M/s Medshare Pharma, Plot No. 04, Special Industrial Zone (APO) Risalpur, KPK.	Nil	Nil

Risk Statement:

Azelaic acid is used for the treatment of skin pigmentation and acne. Falsified product may pose a significant threat to public health as the safety and efficacy of such products cannot be established.



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Action Initiated: -

The Regulatory Field Force has been directed to take necessary action on above mentioned falsified product and is investigating the entire supply chain of this product. The Regulatory Field Force has also been instructed to seize identified falsified product if found in the market.

Advice for Healthcare Professionals: -

DRAP requests healthcare professionals to have increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by batches of above mentioned product.





Any adverse events or quality problems experienced with the use of these products should be reported to National or Provincial pharmacovigilance centers using [Adverse Event Reporting Form](#) or online through this [link](#). Further information on reporting problems to DRAP is available on this [link](#).

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 under intimation to DRAP. Moreover, it is advised to procure medicines from authorized / licensed importers/distributors only.



Drug Regulatory Authority of Pakistan

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