RAPID ALERT

DRAP ALERT No: I/S/01-25-12

PRESENCE OF FALSIFIED MIRZPAN SUSPENSION 100MG/5ML PURPORTEDLY MANUFACTURED BY M/S. MIRAZ PHARMA, KASUR.

Date: 23rd January, 2025

Target Audience:

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

Problem Statement:

Secretary, PQCB Balochistan, has informed DRAP that sample of following product, manufactured by M/s Miraz Pharma, Kasur, has been declared "***Spurious***", "***Unregistered***" and "***Misbranded***" by the Drug Testing Laboratory, Quetta. The sample portion "***Suspension Mirzpan***" contains no Active Pharmaceutical Ingredient (Cefixime), bears a fake registration number in seven digits, and exhibit a pH value of 6.51, which is outside the USP specified range of 2.5 – 4.5. Additionally, the outer packaging contains multiple spelling errors, as well as ambiguous and misleading information. The details of sample are as under:

Product name	Batch/Lot No.	Stated Manufacturer	Mfg. date	Exp. date
Mirzpan Suspension 100mg / 5ml Reg. No. 0326422	007	M/s Miraz Pharma, Plot No. 23, Qasoor Industries, Kasur.	11-2023	11-2025

Risk Statement:

The presence of falsified cefixime suspension poses significant risks to patient health, including potential therapeutic failure, inadequate treatment of bacterial infections, and the development of antibiotic resistance.

DRAP, Islamabad + 92 051 9255969 gsms@dra.gov.pk

Action Initiated: -

The Regulatory Field Force has been directed to conduct surveillance throughout the supply chain to confiscate the mentioned product. 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, and information related to the supplier of such product should be provided to the Regulatory field force (DRAP, Provincial Health Departments and States) to ensure the removal of this product from the circulation.

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 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 Consumers:

Consumers should not use this product and should contact their physician or healthcare provider(s) if they have experienced any problem related to taking or using the above mentioned 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
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DRAP, Islamabad
+ 92 051 9255969
gsms@dra.gov.pk