



## PRODUCT RECALL ALERT

DRAP ALERT NO. N° I/S/10-22-33

### RECALL OF DIAMICRON 80MG TABLET

(MANUFACTURED BY M/S. SERVIER RESEARCH & PHARMACEUTICAL, PAKISTAN PVT LTD LAHORE)

Date: 23<sup>rd</sup> November, 2022

#### 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:

The CDL, Karachi has analyzed the sample of batch No. 1740 of Diamicon 80mg Tablet manufactured by M/s. Servier Research & Pharmaceuticals Pakistan (Pvt) Ltd Lahore, and declared it as “**Substandard**” drug product. Details of the product is as under: -

| Product Name   | Composition        | Manufactured by   | Remarks  |
|--|--------------------|---|--|
| <b>Diamicon 80mg Tablet</b><br><b>Batch No. 1740</b><br>Mfg. Date 04/2022<br>Exp. Date 04/2025 | Gliclazide<br>80mg | M/s. Servier Research &<br>Pharmaceuticals Pakistan<br>(Pvt) Ltd Lahore | <b>Substandard</b><br>doesn't comply<br>dissolution test |

#### Action Initiated: -

The company is directed to immediately recall the defected batch of product from the market. All Pharmacists and chemists working at distributions and Pharmacies should **immediately check** their stocks and stop supplying this batch of product. The remaining stock should be quarantine and return to the supplier / company. Regulatory field force of all federating units (DRAP, Provincial Health Departments and States) have also increased surveillance in the market to ensure the effective recall of defective product(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.

