PRODUCT RECALL ALERT

DRAP ALERT NO. Nº I/S/02-23-11

RECALL OF CALCIUM GLUCONATE INJECTION (B. NO. 220325)

(MANUFACTURED BY M/s. CHINA NATIONAL M/H SHANGHAI CHINA)

Date: 23rd February 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

Alert Summary:

Drug inspector Quetta took the sample of Calcium Gluconate Injection Batch no. 220325 which has declared as **Misbranded** by Provincial Drug Testing Laboratory, Quetta. Details of the product is given as under:

Product Name	**Manufactured by**	**Remarks**
Calcium Gluconate Injection (Reg# 010084) **Batch No. 220325** Mfg. Date: 03-22 Exp. date: 03-25	Ms. China National M/H Shanghai China. Sole Agent: M/s. Shaheen Agency, Karachi.	• The sample portion "Inj. Calcium Gluconate" ampoule is printed with delible ink which is easily removable rather than mandatory requirement is indelible ink. • Sample printed label of ampoule already not readable, hence the product violates the provisions of Drug Act 1976.

Risk Statement:

Injection Calcium gluconate is a lifesaving drug which is indicated for pediatric and adult patients for the treatment of acute symptomatic hypocalcemia. Wrongful use /misleading information due to delible printing upon label of Injection Calcium Gluconate, may disturb the patient's body calcium balance and may lead to adverse reactions including but not limited to following:

(i) Arrhythmias with Concomitant Cardiac Glycoside Use.

(ii) End-Organ Damage due to Intravascular Ceftriaxone-Calcium Precipitates.

(iii) Tissue Necrosis and Calcinosis.

(iv)Hypotension, Bradycardia, and Cardiac Arrhythmias.

Action Initiated: -

The sole agent / registration holder has been directed to **immediately recall** the defected batch of product from the market by Secretory Provincial Quality Control Board, Quetta. All pharmacists and chemist working at distributions and pharmacies should **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 all federating units (DRAP, Provincial Health Departments and States) have also increased 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، موثر اور معیاری اشیائے علاج

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