File No. PSUR-13011(14)/1/2025-eoffice
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General (India)
(Post Marketing Drugs Safety Monitoring Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 10 NOV 2026

To,

All State/UT Licensing Authorities

Sub: - Lithium Carbonate related Drug Reaction with Eosinophilia and Systemic symptoms Syndrome (DRESS) - Recommendations for the change in Prescribing Information Leaflets (PILs) - Reg

Sir,

A safety signal of **Drug Reaction with Eosinophilia and Systemic symptoms Syndrome (DRESS)** associated with Lithium Carbonate is identified after evaluation of Periodic Safety Update Report (PSUR) data of Lithium Carbonate formulations by CDSCO. The signal was examined in conjunction with the Individual Case Safety Reports (ICSRs) of Lithium Carbonate formulations available in the Pharmacovigilance Programme of India (PvPI) database which was discussed in the 9th Signal Review Panel (SRP) of the Pharmacovigilance Programme of India (NCC-PvPI), held on 29th November 2016. Based on the combined findings of the CDSCO PSUR data evaluation and the PvPI ICSR assessment, the SRP made a recommendation to CDSCO to take necessary measures to incorporate "**Drug Reaction with Eosinophilia and Systemic symptoms Syndrome (DRESS)**" as an adverse drug reaction in to the Prescribing Information Leaflet (PIL) of the Lithium Carbonate based medical products marketed in the country.

The aforementioned recommendations of NCC-PvPI were subsequently reviewed by the Subject Expert Committee (SEC) on Neurology & Psychiatry during its meeting held on 17.03.2017 at CDSCO-HQ, New Delhi. After detailed deliberations, the committee recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers to incorporate ***"Drug Reaction with Eosinophilia and Systemic symptoms Syndrome (DRESS) associated with Lithium Carbonate as***

an Adverse Drug Reaction (ADR) in the corresponding Prescribing Information Leaflet (PIL) of the drug."

The recommendation of the SEC has been considered by this office. Accordingly, you are requested to direct the manufacturers of Lithium Carbonate formulations under your jurisdiction to mention ***"Drug Reaction with Eosinophilia and Systemic symptoms Syndrome (DRESS)"*** as an adverse drug reaction in the Package insert/Promotional Literature of the drug.

Action taken in this regard may be intimated to this office.

Yours faithfully,

(Dr.Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Copy for information & follow-up: -

1. All Zonal / Sub Zonal Offices of CDSCO and CDSCO-HQ

Copy for information to: -

2. JS(R), Nirman Bhawan, MoHFW, New Delhi-110002.

Copy to:-

3. PvPI, Indian Pharmacopeia Commission, Ghaziabad.